EXHIBIT 1

US006582408B1

(12) **United States Patent**
Buch-Rasmussen et al.

(10) **Patent No.: US 6,582,408 B1**
(45) **Date of Patent: Jun. 24, 2003**

(54) **MEDICAL DEVICE**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/349,748**

(22) Filed: **Jul. 8, 1999**

Related U.S. Application Data

(60) Provisional application No. 60/098,707, filed on Sep. 1, 1998.

(30) **Foreign Application Priority Data**

Jul. 8, 1998 (DK) ..... PA 1998 00910
Nov. 17, 1998 (DK) ..... PA 1998 01501

(51) **Int. Cl.**[7] **A61M 5/00**
(52) **U.S. Cl.** **604/232**; 604/187
(58) **Field of Search** 604/186, 187, 604/232, 188, 192, 195, 207–218, 200, 201, 228, 233, 234

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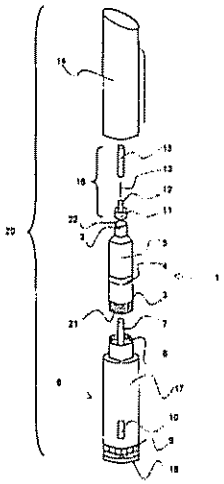
(57) **ABSTRACT**

The present invention relates to a medication delivery device comprising a cartridge assembly, a dosing assembly and optionally a needle assembly. The cartridge assembly comprises a cartridge having a stopper adapted to receive a plunger. Furthermore, the cartridge assembly has one end sealed with a pierce able sealing, said end comprising coupling device for engaging a needle assembly, and another end comprising coupling device for engaging the dosing assembly. The dosing assembly comprises a plunger and has coupling device for engaging the cartridge assembly. The cartridge assembly and the dosing assembly are coupled together for delivering selected doses of medication. The device further comprises mechanism for securing that the plunger abuts on the stopper during use of the device, in particular when the dosing assembly is releasable coupled to the cartridge assembly. The securing mechanism is preferably a mechanism for preventing the cartridge assembly from being inadvertently released from the dosing assembly. The cartridge is preferably molded from a plastic material, such as a transparent material, and may be housed in a cartridge housing for protection of the cartridge. The medication delivery device is especially suitable for delivering insulin, growth hormone or the like medicines.

11 Claims, 2 Drawing Sheets



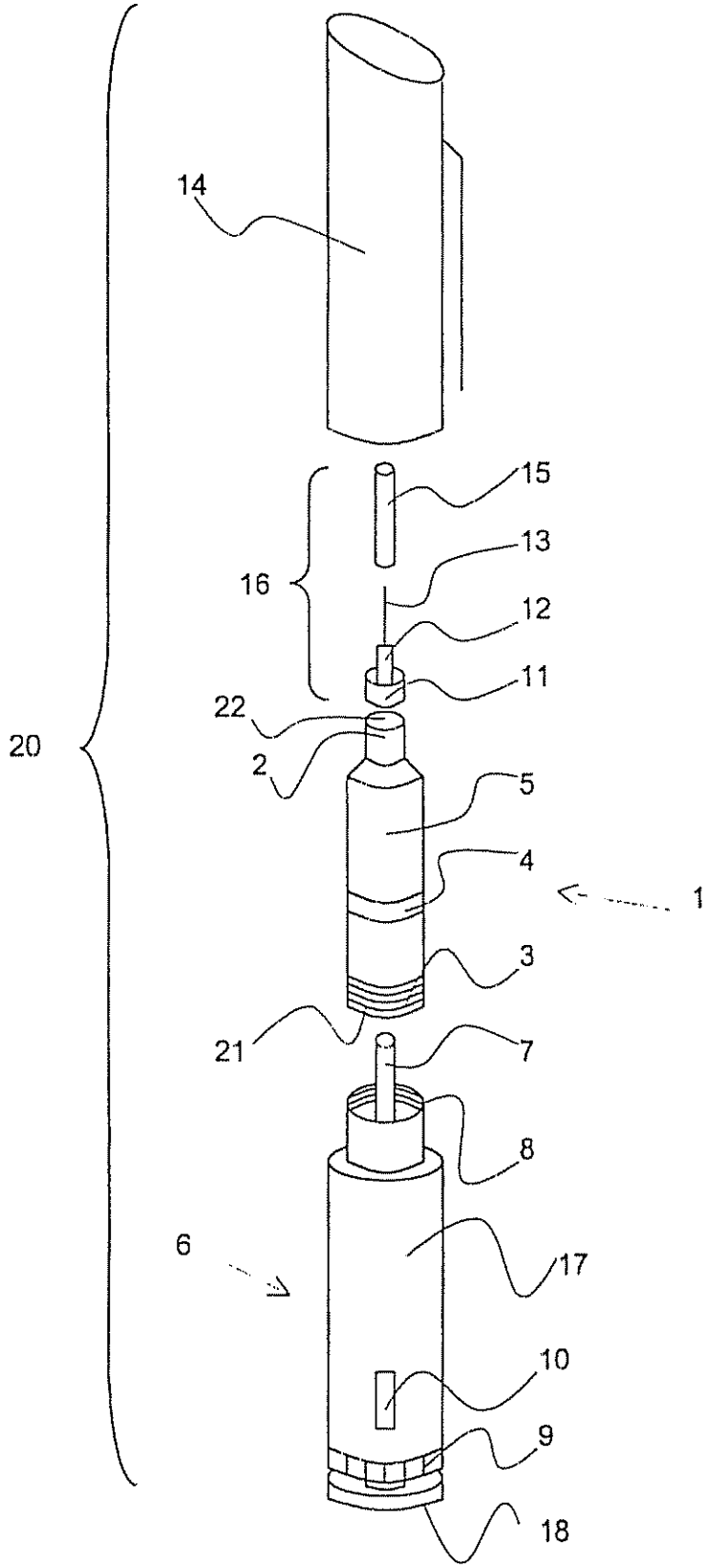


Fig. 1

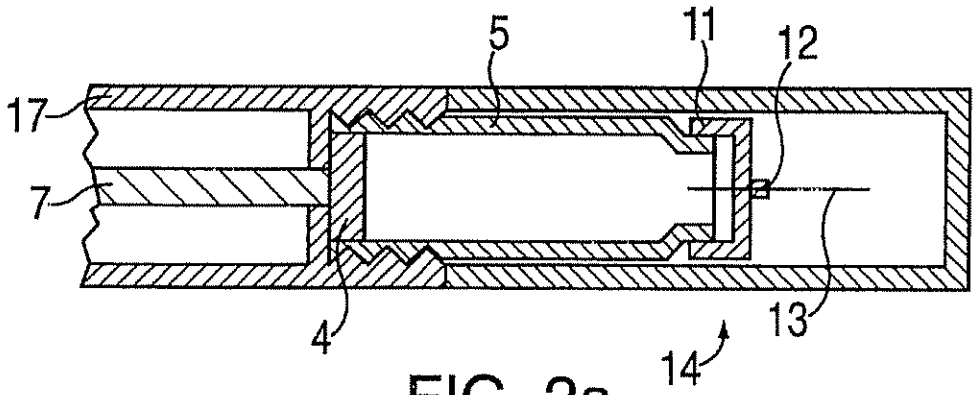


FIG. 2a

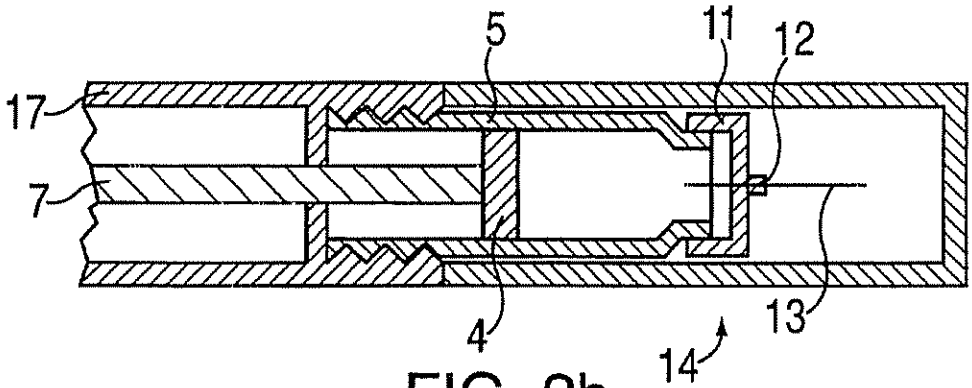


FIG. 2b

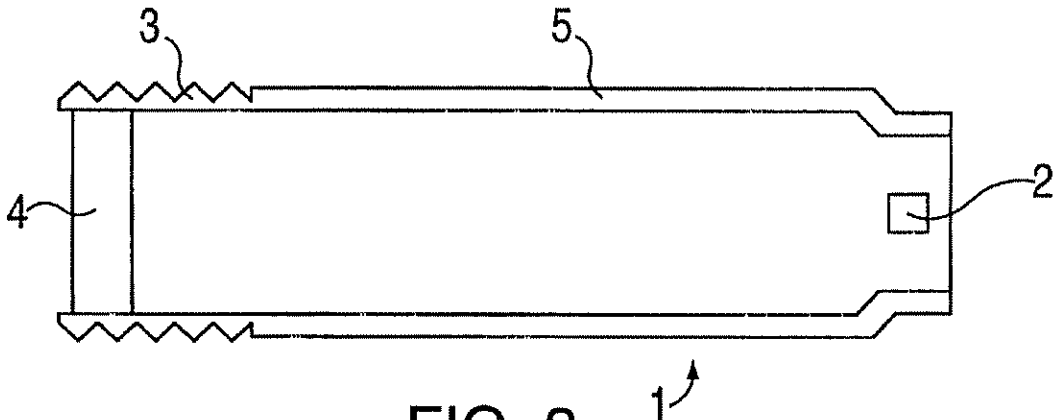


FIG. 3

MEDICAL DEVICE

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims priority under 35 U.S.C. 119 of Danish application serial nos. PA 1998 00910 filed Jul. 8, 1998, PA 1998 01501 filed Nov. 17, 1998, and U.S. Provisonal application serial No. 60/098,707 filed Sep. 1, 1998, the contents of which are fully incorporated herein by reference.

BACKGROUND

Some medication, such as insulin is self-administered. The typical diabetes patient will require injections of insulin several times during the day. The required insulin dose will vary from patient to patient, and will for each patient often also vary during the day. Each patient will often establish a regimen for the insulin administration adjusted to his or her insulin need as well as lifestyle. Medication delivery pens have been developed to facilitate the self-administration of medication, such as insulin.

One prior art medication delivery pen includes a pen body assembly comprising a medication cartridge and a plunger device. A needle assembly may be connected to the pen body assembly. The medication is delivered by moving or pressing a plunger in the direction of the needle assembly, thereby delivering the medication. When the medication in the cartridge is exhausted, the pen body assembly is discarded. Depending on the medication needs for each individual the medication in the cartridge will last for several days. During this period the needle assembly will often have to be replaced by a new assembly or new needle due to increasing bluntness of the needle making injections painful for the patient.

Due to the environmental and economical reasons medication delivery pens were developed, for which pens only a part of the pen was discarded after medication exhaustion, such as the cartridge only.

An example of prior art pens is disclosed in EP 0 688 571 wherein a medication delivery pen has a reusable pen body assembly and a disposable cartridge assembly that are threadedly engageable with one another. The disposable cartridge assembly includes a plunger and can releasable receive a needle cannula assembly through a threaded coupling. A driving means in the pen body assembly engages the plunger after engagement of the pen body assembly and the cartridge assembly, whereby the pen is ready for dosing the medicine within the cartridge. The cartridge holder assembly can be disassembled from the pen body assembly after the medication therein has been exhausted, discarded and replaced.

However, a drawback of the above-mentioned pen is that the driving means of the pen body may be disengaged from the plunger of the cartridge during normal use resulting in inaccurate dosing of the medicine.

For the device disclosed in EP 0 688 571, the needle assembly will often have to be replaced independently of replacement of the cartridge. When releasing the needle assembly from the cartridge assembly the cartridge assembly may inadvertently be released or partly released from the pen body assembly. Thereby the driving means of the pen body may be disengaged from the plunger of the cartridge. In particular if the pen body assembly is only partly released from the cartridge assembly the user will most probably not be aware of the disengagement but will receive only a portion or even nothing of the medicine.

Even pens with differently pitched threaded couplings and/or threaded couplings having different diameters whereby the force exerted to fasten and/or release one coupling is greater than the force necessary for the other coupling present this problem. It is easy to imagine that a small obstruction (a sandskorn, for example) to the smoothest going coupling will necessitate a greater force to fasten/release that coupling which force tends towards the force necessary for the other coupling.

Accordingly, it is an object of the present invention to provide a medication delivery device with which the inadvertent disengagement of the driving means and plunger means from the plunger or stopper in the cartridge is avoided.

SUMMARY OF THE INVENTION

According to a first aspect of the invention a medication delivery device is provided which comprises

a cartridge assembly, having one end sealed with a pierce able sealing, said end of the cartridge assembly comprising coupling means for releasable mounting a needle assembly, and comprising a cartridge having a stopper adapted to receive plunger means,

a dosing assembly comprising plunger means,

and optionally a needle assembly,

wherein the cartridge assembly and the dosing assembly are coupled together, and the device further comprises means for securing that the plunger means abuts on the stopper during use of the device.

In a preferred embodiment the dosing assembly is reusable and the cartridge assembly is disposable, and accordingly, a second aspect of the present invention is a medication delivery device wherein the dosing assembly is releasable coupled to the cartridge assembly.

By the term "use of the device" is meant the normal use, including metering and delivering the medication, removing a cap from the cartridge assembly and/or needle as well as attaching and releasing the needle assembly. It is understood that the plunger means must disengage the stopper when the cartridge assembly is deliberately released from the dosing assembly because the medication in the cartridge has been exhausted and the cartridge assembly is to be discarded. In this situation the plunger means is to be retracted to the dosing assembly before assembling the device with a new cartridge assembly.

Securing the abutment of the plunger means on the stopper during use of the medication delivery device, in particular when the needle assembly is coupled to and/or decoupled from the cartridge assembly, may be carried out by a variety of means. In a preferred embodiment the abutment is secured by preventing the cartridge assembly from being inadvertently released from the dosing assembly.

Furthermore, it is a preferred aspect of the invention to provide a medication delivery device, which device is arranged for securing that the plunger means abuts on the stopper during coupling and/or decoupling of the needle assembly.

In one embodiment of the invention the dosing assembly is coupled to the cartridge assembly at the end of the cartridge assembly opposite the means for mounting the needle assembly, and the plunger means is a rod element adapted to exert an axial movement of the stopper towards the sealed end of the cartridge.

Accordingly, it is an aspect of the present invention to provide a medication delivery device, wherein the means for coupling the dosing assembly and the cartridge assembly

together are such that the coupling and/or decoupling of the needle assembly does not cause an axial movement of the cartridge assembly with respect to the dosing assembly. In this way it is assured that the rod element does not disengage the stopper in the cartridge when the user attaches the needle assembly or removes it after use. Thereby the user can be confident of the accuracy of the dosage selected.

The means for coupling the dosing assembly and the cartridge assembly together may be any suitable coupling, preferably a releasable coupling. Examples of the coupling are snap locks, such as snap locks with guidewire and sideways snap locks, snap locks released through threads, bajonet locks, luer locks, hinged locks, threaded locks and any suitable combinations thereof.

In particular, when the cartridge assembly is released from the dosing assembly through a movement including an axial movement, such as through a threaded coupling, it is preferred that the means for releasable coupling the needle assembly and the cartridge assembly together are such that the coupling and/or decoupling of the needle assembly cannot cause an axial movement of the cartridge assembly with respect to the dosing assembly. Thus, in that respect examples of the preferred couplings between the needle assembly and the cartridge assembly include releasable snap locks. Another preferred embodiment includes a safety on the coupling between the dosing assembly and the cartridge assembly, such as hinge on the coupling or a threaded coupling releasable only after exerting an axial pressure on the coupling.

According to the invention preferred combinations of couplings between the dosing assembly and the cartridge assembly and between the needle assembly and the cartridge assembly, respectively, are a threaded coupling combined with a snap coupling, a bajonet lock or a luer lock combined with a snap lock, or a snap lock combined with a snap lock, or any other combination for which the couplings are independently working.

Another aspect of the present invention is a cartridge assembly for use in the medication delivery device according to the invention. The cartridge assembly comprises a cartridge for the medication to be delivered. The cartridge assembly has one end sealed with a pierce able sealing, said end of the cartridge assembly comprising coupling means for releasable mounting a needle assembly, and another end comprising coupling means adapted to engage a dosing assembly. Furthermore, the cartridge comprises a stopper.

The cartridge assembly may further comprise a housing for protecting at least a part of the cartridge assembly.

In a preferred embodiment at least one of the coupling means of the cartridge assembly is unitarily molded with the cartridge, and in a more preferred embodiment all the coupling means are unitarily molded with the cartridge. In the latter case the cartridge assembly may be comprised of just one part, i.e. the cartridge including the coupling means.

In another embodiment the invention relates to a medication delivery device for transferring medication from the cartridge into a syringe with a needle. In this embodiment the coupling means for engaging the needle assembly may be replaced by coupling means for engaging the syringe, or coupling means for both may be provided. The coupling means may be a syringe holder, for example a cylinder coupled to the cartridge comprising a central bore for receiving the syringe. The syringe is coupled to the cartridge having the needle piercing the sealing. By activation of the dosing means the metered amount of medication is driven into the syringe. The syringe is then ready for injection after being removed from the cartridge.

DRAWINGS

FIG. **1** is an exploded perspective view of the medication delivery device.

FIG. **2** is a cross-sectional view showing part of the medication delivery device, *2a* immediately after assembling before the first injection, and *2b* after some time of use.

FIG. **3** is a cross-sectional view showing the cartridge before assembling of the medication delivery device.

DETAILED DESCRIPTION OF THE INVENTION

A medication delivery device in accordance with the present invention is identified generally by the numeral **20** in FIG. **1** and **2**. Medication delivery device **20** includes a dosing assembly **6**, and cartridge assembly **1**, a needle assembly **16** and a cap **14**.

The dosing assembly **6** is illustrated in FIGS. **1** and **2**. It is understood, however, that the dosing assembly **6** according to the invention may be any suitable dosing unit including plunger means and, accordingly, that variations from the depicted embodiment may be provided, and are considered to be within the scope of this invention. In the depicted embodiment, the dosing assembly **6** includes a cylindrical housing **17** surrounding the plunger means of the dosing unit and having opposed proximal and distal ends.

In one aspect of the invention the plunger means comprises a rod element **7** which is adapted to engage the stopper **4** of the cartridge assembly **1**. The rod element **7** advances axially into the cartridge **5** during injections. The dosing assembly may have any suitable driving means for advancing the rod element **7**.

The dosing unit **6** preferably also comprises scale means **10** indicating the dosing quantity selected by activating the dose setting means **9** for defining specified selected doses of medication to be delivered. The selected dose may be delivered by actuating the actuator button **18**. The actuator button is part of the driving means of the dosing assembly exerting its force on the rod element **7**.

The dosing assembly further comprises coupling means **8** adapted for engagement with the cartridge assembly. The coupling means **8** may be internal or external couplings. In a preferred embodiment the coupling **8** is an internal coupling.

The cartridge assembly **1** is illustrated in FIGS. **1** and **2**, and in greater detail in FIG. **3**. In FIG. **1** cartridge assembly **1** includes a molded cartridge **5** extending from proximal end **21** to distal end **22**.

At the distal end **22** of the cartridge assembly **1** is provided coupling means **2** for releasable mounting a needle assembly **11**. At the proximal end **21** of the cartridge assembly **1** is provided coupling means **3** for mounting a dosing assembly **6**. The coupling means are as described above.

Cartridge **5** also comprises a stopper **4** in sliding fluid tight engagement within said cartridge **5**. The stopper **4** is adapted to receive the plunger means, such as a rod element **7** of the dosing assembly **6**.

The cartridge assembly **1** may further comprise a housing for protecting some or all of the cartridge **5**. When the cartridge assembly **1** includes a housing, one or both of the couplings **2, 3** of the cartridge may be molded unitarily with the housing.

In a preferred embodiment at least one of the couplings **2, 3** is molded unitarily with the cartridge **5**, minimising the

total number of parts of the device and thereby the production costs. Also, a very precise coupling is obtained, since no further steps are to be taken to attach the coupling means to the catridge.

Instead of the protective housing the cartridge **5** may have integrally molded reinforcements of the cartridge wall.

The depicted cartridge **5** is cylindrical having couplings **2**, **3** at opposed ends. However, the cartridge may obtain any suitable form and the cross-section may be circular or non-circular, such as substantially triangular or oval.

In FIG. **1** and FIG. **2** the couplings **2**, **3** are opposing each other having the same axis. However, the axis of coupling **2** may be arranged to be separate from coupling **3**, that is in any angle with respect to the axis of coupling **3**. Thus, the axis of coupling **2** may be perpendicular to the axis of coupling **3**, or they may be parallel but not overlapping.

A suitable choice of material allows the cartridge to be at least partly transparent, whereby the user can see whether any content, such as a liquid is left in the cartridge.

Referring to FIG. **3** the coupling means of the cartridge are shown in greater detail. The coupling means **3** is an external thread, whereas the coupling means **2** is a recess for a snap lock of the needle assembly. Both coupling means are molded unitarily with the cartridge.

The device according to the invention may include a protective cap **14** that is removably mounted over the cartridge assembly **1** and/or the needle **11** and which is removed before injection of the medication in the cartridge **5**. The cap further ensures that the content of the cartridge is protected against sunlight.

The various parts of the medication delivery device are advantageously made of plastics, e.g. by injection moulding.

The medication delivery device **20** may further comprise any appropriate needle assembly **11**, such as a double ended needle **13** having opposed proximal and distal points and a lumen extending axially therebetween.

A mounting hub **12** is engaged on the needle **13** and is removably connected to the coupling means **2** at the needle end of the cartridge assembly. The relative location of the mounting hub **12** ensures that the proximal point of the needle **13** will pierce the sealing when the mounting hub **12** is engaged with the coupling means **2** on the cartridge assembly **1**.

The needle assembly **11** may further comprise a removable shield or cap **15** for protecting against accidental needle sticks.

The device according to the invention is suitable for delivering pre-set dosages of insulin, it is however understood that the device is suitable for the injection of pre-set dosages of other liquids.

In use the user will set the dose by means of the dose setting means **9**. Before activating the actuator button **18** the cap **14** must be removed from the cartridge assembly **1** whereby the device **20** is prepared for an injection. The injection is effected by activating the actuator button **18**, which again will effect the stopper **4** to be moved towards the needle at the sealed end **22** of the cartridge **5**, thereby delivering the desired pre-set dosage. A subsequent dosage of medication will be set in exactly the same manner as described above. However, for such a subsequent dosage, the rod element **7** and the stopper **4** will be in a partly advanced position as starting point. Dose setting and injections can be carried out until all of the medication has been used.

What is claimed is:

1. A medication delivery device comprising:

a cartridge assembly comprising a cartridge having a pierceable seal at one end and a moveable stopper at an opposite end;

a dosage assembly comprising a plunger means for acting on the stopper; a mechanism for setting a specified dose; and a drive means for advancing the plunger means to deliver the specified dose;

a needle assembly;

a first coupling means for coupling and uncoupling the needle assembly to and from the cartridge assembly;

a second coupling means for coupling and uncoupling the cartridge assembly to and from the dosage assembly;

wherein the first coupling means comprises a snap lock; and

wherein the second coupling means is selected such that when a user grasps the needle assembly and applies a force to couple it to and to uncouple it from the cartridge assembly, while simultaneously grasping the dosage assembly and applying an equal but opposite force thereto, the cartridge assembly cannot not move axially with respect to the dosage assembly.

2. The medication delivery device of claim **1**, wherein the first coupling means comprises a means for coupling or uncoupling the needle assembly through an axial movement of the needle assembly relative to the cartridge assembly and the second means comprises a threaded means.

3. The medication delivery device of claim **2**, wherein the cartridge assembly comprises a housing for receiving the cartridge and wherein the snap lock is an integral part of the needle assembly.

4. A medication delivery device upon which a needle assembly can be mounted, the device comprising:

a cartridge assembly comprising a cartridge having a movable stopper at one end and a pierceable seal at an opposite end;

a dosage assembly comprising a mechanism for setting a specified dose, a plunger means for abutting the moveable stopper, and a drive means for driving the plunger means to deliver the set doseage;

a first coupling means for coupling and uncoupling the cartridge assembly to and from the dosage assembly; and

a second coupling means for coupling and uncoupling a needle assembly to and from the cartridge assembly;

wherein the first and second coupling means are selected so that when a user grasps the needle assembly and applies force to the needle assembly to couple and uncouple it from the device while simultaneously grasping the dosage assembly and applying a equal and opposite force to the dosage assembly, the dosage assembly cannot move relative to the cartridge assembly, thereby ensuring that the plunger means remains abutted against the stopper; and

wherein the first or second coupling means comprises a snap lock.

5. The medication delivery device recited in claim **4**, wherein the second coupling means comprises a threaded coupling means and wherein the second coupling means comprises a means for coupling and uncoupling through an axial movement of the needle assembly relative to the cartridge assembly.

6. The medication delivery device of claim **4**, wherein the first coupling means comprises a means for uncoupling

through an axial movement of the cartridge assembly relative to the dosing assembly.

7. The medication delivery device of claim 4, wherein the first coupling means comprises a threaded coupling means.

8. The medication delivery device of claim 4, wherein the cartridge assembly comprises a housing to accommodate the cartridge and wherein the second coupling means comprises a means for axially coupling or uncoupling the needle assembly from the cartridge assembly.

9. The medication delivery device of claim 4, wherein the second coupling means comprises a threaded coupling means.

10. A medication delivery device comprising:

a cartridge assembly comprising:

a housing capable of housing a removable cartridge that has a pierceable seal at one end, is filled with medication, and has a moveable stopper at an opposite end that when moved toward the medication pressurizes the medication; and

a needle mounting means for mounting a needle on the cartridge assembly;

a dosage assembly for delivering a set dose of medication, comprising:

a plunger means for moving the stopper, a dose setting means for setting a dose, and a drive means for driving the plunger means to deliver the set dose, wherein after a portion of medication is expelled from the cartridge, the plunger means abuts the stopper;

a first means for coupling and uncoupling a needle assembly to and from the cartridge assembly;

a second means for coupling and uncoupling the dosage assembly to and from the cartridge assembly;

wherein the first and second coupling means are chosen so that when a user simultaneously grasps the dosage assembly and the needle assembly and applies a force to the needle assembly to couple (or uncouple) the needle to or from the device the cartridge assembly is positively precluded from moving axially relative to the cartridge assembly; and

wherein at least the first or the second coupling means comprises a snap lock.

11. A medication delivery device comprising:

a cartridge assembly for housing a removable cartridge containing a medication;

a needle assembly;

a dosage assembly comprising a mechanism for setting a dosage less than the full amount of medication contained in the cartridge;

a first coupling means for coupling and uncoupling the needle to and from a removable cartridge housed in the cartridge assembly; and

a second coupling means for coupling and uncoupling the cartridge assembly to and from the dosage assembly;

wherein the first coupling means comprises a snap lock; and

wherein the second coupling means is chosen so that when a user couples or uncouples the needle assembly from the cartridge by grasping the needle assembly and the dosage assembly simultaneously and applying force to both, the second coupling means prevents axial movement of the cartridge assembly relative to the dosage assembly.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 6,582,408 B1
DATED : June 24, 2003
INVENTOR(S) : Buch-Rasmussen et al.

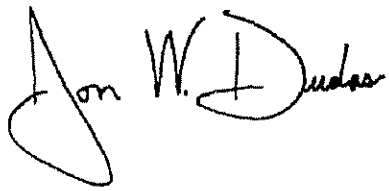
It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 6,
Line 23, "cannot not move" should read -- cannot move --.

Column 8,
Line 7, "cartridge assembly" should read -- dosage assembly --.

Signed and Sealed this

Thirteenth Day of September, 2005



JON W. DUDAS
Director of the United States Patent and Trademark Office

EXHIBIT 2

UNITED STATES INTERNATIONAL TRADE COMMISSION

FAX COVERSHEET

Setting Target Date -337-TA-572

TO: Delbert R. Terrill, Jr. Esq./ White & Case LLP 202-639-9355	
Paul Berghoff, Esq./ McDonnell, Boehnen, Hulbert & Berghoff LLP - 1-312-913-0002	
TO: Arthur Wineburg, Esq. Tobias Zimmerman, Esq. Colleen Coylee, Esq. AKIN GUMP STRAUSS HAUER & FELD	
FAX: 202-887- 4288	

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of	
CERTAIN INSULIN DELIVERY DEVICES, INCLUDING CARTRIDGES HAVING ADAPTORS TOPS AND COMPONENTS THEREOF	Inv. No. 337-TA-572

Order No. 5: Denying Respondents' Motion for Sanctions

By publication of a notice in the *Federal Register* on June 9, 2006, pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, the Commission instituted this investigation to determine:

> [W]hether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain insulin delivery devices, including cartridges having adaptor tops, or components thereof, by reason of infringement of claims 1-3, 5-7, 11, 18, or 19 of U.S. Patent 5,693,027, and whether an industry in the United States exists or is in the process of being established as required by subsection (a)(2) of section 337.

71 Fed. Reg 33484 (2006).

The complainants are: Novo Nordisk A/S of Denmark; Novo Nordisk Inc. of Princeton, New Jersey; and Novo Nordisk Pharmaceuticals Industries, Inc. of North Carolina. The Commission named as the respondents: Sanofi-Aventis Deutschland GmbH of Germany; Sanofi-Aventis of France; and Aventis Pharmaceuticals, Inc. of Bridgewater, New Jersey. The Commission Investigative Staff is also a party in this investigation. *Id.*

On October 5, 2006, pursuant to 19 C.F.R. 210.21(a)(1), complainants filed their "Motion to Withdraw the Complaint and Terminate the Investigation As to All Parties." Motion Docket No. 572-4.

On October 13, 2006, respondents filed their "Motion to Sanction Complainants." Motion Docket No. 572-5. Respondents argue that complainants lacked a good faith basis for filing the complaint upon which this investigation is based, and withdrew the complaint only after respondents independently discovered prior art (developed by complainants' own company) that invalidates the '027 suit patent. Respondents request an order requiring complainants to pay respondents' litigations costs, and also barring complainants from asserting the '027 patent at the Commission. Motion at 1-3. It is argued that the Commission's authority to issue such an order resides in 19 C.F.R. § 210.4(d), and in "the inherent powers of the [Commission] to manage and administer the conduct of parties to ITC investigations and accepted principles of jurisprudence . . . ." *Id.* at 1.

On October 23, 2006, complainants filed their response in opposition to the motion for sanctions. Complainants argue that respondents are unable to support their motion with legal authority, and argue that they withdrew their complaint for reasons unrelated to alleged prior art discovered by respondents.

On October 25, 2007, the Commission Investigative Staff of the Office of Unfair Import Investigations filed its response in opposition to respondents' motion for sanctions.

On November 3, 2006, respondents filed a motion for leave to reply and a reply.[1] On November 10, 2006, complainants filed an opposition to respondents' motion for leave.

[1]Respondents' motion for leave is docketed out of sequence as Motion No. 572-21.

Respondents' motion for leave is GRANTED.

Notwithstanding respondents' arguments concerning the inherent powers of the Commission to regulate the conduct of its investigations, the Commission's Rules set forth the procedures to be used in determining whether or not to issue sanctions in connection with the filing of documents, such as a complaint. The so-called "safe harbor" provision of Commission Rule 210.4 dictates that respondents' motion for sanctions must be denied.

In particular, Commission Rule 210.4 requires that a pleading may not be filed for an improper purpose and must be supported by a reasonable inquiry on the part of the person filing the pleading. *See* 19 C.F.R. § 210.4(c). However, sanctions cannot automatically be requested any time a party believes that this Rule has been violated. Rather, if a party seeks to file a motion for sanctions due to an alleged violation of the Rule, the prospective movant must first serve the motion on the nonmoving parties. The party or person against whom sanctions might be sought then has seven days to withdraw or correct the challenged document. If withdrawal or correction does not occur within that period, the movant is free to file the motion for sanctions. *See* 19 C.F.R. § 210.4(d)(1)(I). *See Certain Hardware Logic Emulation Systems and Components Thereof*, Inv. No. 337-TA-383, Commission Opinion on Appeals of ALJ Order No. 96 at 19 (May 27, 1998); *Certain Semiconductor Light Emitting Devices, Components Thereof, and Products Containing*, Inv. No. 337-TA-444, Order No. 6 at 4 (June 27, 2001)(following the aforementioned Commission Opinion); *see also Certain Point of Sale Terminals and Components Thereof*, Inv. No. 337-TA-524, Commission Opinion at 13 (Aug. 23, 2006)(The Commission declined to issue sanctions based on "inherent authority" outside Commission Rule 210.4).

In this instance, it has not been established that respondents followed the "safe harbor" provision of Commission Rule 210.4 by serving their motion upon complainants and the Staff seven days before service upon the Commission, presumably with a request to withdraw the complaint. In any event, complainants moved to withdraw their complaint 10 days before respondents filed the pending motion for sanctions.

In addition, the substance of respondents' motion for sanctions requires a determination concerning the meaning of asserted patent claims and their relationship to alleged prior art. This investigation has not reached a state at which such determinations can be made.

Accordingly, respondents' Motion No. 572-5 for sanctions is DENIED.

Sidney Harris
Administrative Law Judge

Issued: January 29, 2007

EXHIBIT 3

Docket No. 5533.200-US

AF/3763

SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP
FOUR TIMES SQUARE
NEW YORK 10036-6522
(212) 735-3000
FAX: (212) 735-2000

Applicant(s) : Buch-Rasmussen et al.

Serial No. : 09/349,748 Examiner: Sirmons, K.

Filed : July 8, 1999 Art Unit: 3763

Title : Medical Device

AMENDMENT TRANSMITTAL
AND REQUEST FOR EXTENSION OF TIME

Date: December 10, 2001

Box AF
Assistant Commissioner For Patents
Washington, DC 20231

Sir:

I hereby certify that this paper is being deposited with the United States Postal Service, as first class mail, in an envelope addressed to: Assistant Commissioner for Patents, Washington, DC 20231, on December 10, 2001.

Robert B. Smith Reg. No. 28,538

Robert B. Smith
Signature

December 10, 2001
Date

Transmitted herewith is an Amendment in the above-identified application.

1. ( ) No additional fee is required.

01/14/2002 CCHAU1 00000092 192385 09349748
01 FC:115 110.00 CH

2. ( ) The fee has been calculated as shown below:

Claims remaining	Prior Paid Claims		Extra		Rate		Fee
Total:	minus (at least 20)	=		@	$18	=	$
Independent	minus (at least 3)	=		@	$80	=	$____

TOTAL ADDITIONAL FEE: $

3. (X) An extension of time to respond to the PTO Communication dated August 24, 2001 is hereby requested. The required fee is indicated below:

Within first month:	(X)	$ 110
Within second month	( )	$ 400
Within third month	( )	$ 920
Within fourth month	( )	$1,440
Within the fifth month	( )	$1,960

4. ( ) Enclosed please find a check in the amount of $ 0.00 representing (a) additional claims fee ($ 0) and (b) the extension fee ($ 0).

5. (X) The Commissioner is hereby authorized to charge the amount of $ 110.00 representing (a) additional claims fee ($); and (b) the extension fee ($ 110) to deposit account No. 19-2385. A copy of this sheet is enclosed for such purpose.

6. (X) In the event that an extension of time is required and applicant has inadvertently overlooked the need to request a petition and file the fee, the applicant hereby petitions for such extension of time. The Commissioner is authorized to charge the required fee to deposit account No. 19-2385. A copy of this sheet is enclosed for such purpose.

7. (X) The Commissioner is hereby authorized to charge payment of any additional fees required in connection with this application, and credit any overpayment, to deposit account No. 19-2385. A copy of this sheet is enclosed.

Skadden, Arps, Slate, Meagher & Flom

By Robert B. Smith

Robert B. Smith
Registration No. 28,538
Attorneys for Applicant(s)
(212) 735-3020

Docket No. 5533.200-US #14

Amdt C
S. Byce
1/17/02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s)	:	Buch-Rasmussen et al.	
Serial No.	:	09/349,748	Examiner: Sirmons, K.
Filed	:	July 8, 1999	Art Unit: 3763
Title	:	Medical Device	

I hereby certify that this paper is being deposited with the United States Postal Service, as first class mail, in an envelope addressed to: Assistant Commissioner for Patents, Washington, DC 20231, on December 10, 2001.

Robert B. Smith — Reg. No. 28,538

Robert B. Smith — December 10, 2001
Signature — Date

December 10, 2001

AMENDMENT AFTER FINAL REJECTION

Box AF
Assistant Commissioner For Patents
Washington, DC 20231

Sir:

In response to the Office Action dated August 24, 2000, the applicants respectfully request entry of the following amendments, to render the claims allowable or at least in better form for appeal:

IN THE CLAIMS:

Cancel claims 2-18, 20, and 24.

Replace claims 1, 21, 25, 28, and 31 with the following claims:

1. (Twice Amended) A medication delivery device comprising:

a cartridge assembly having a distal end and a proximal end, said distal end of the cartridge assembly comprising coupling means for releasably mounting a needle assembly, and said cartridge assembly comprising a cartridge having one end sealed with a pierceable seal and having a stopper adapted to receive a plunger means,

a dosing assembly comprising a plunger means for acting on said stopper, a mechanism for setting a specified dose, and a driving means for advancing said plunger means to deliver the set dose, and

a needle assembly including a coupling means for engaging the coupling means of said cartridge assembly to form a releasable coupling between said needle assembly and said cartridge assembly,

wherein the cartridge assembly and the dosing assembly are releasably coupled together, and wherein the combination of couplings between the dosing assembly and the cartridge assembly, and between the needle assembly and the cartridge assembly, respectively, is selected to ensure that the force applied to couple and decouple said needle assembly to and from said cartridge assembly does not cause said dosing assembly to move away from said cartridge assembly during coupling and decoupling of said needle assembly, such that said plunger means remains in abutment with said stopper during such coupling and decoupling.

21. (Amended) A medication delivery device according to claim 1, wherein the dosing assembly is released from the cartridge assembly through a movement including an axial movement.

25. (Amended) A medication delivery device according to claim 1, wherein the cartridge assembly comprises a housing for receiving a cartridge.

28. (Amended) A medication delivery device comprising:

a cartridge assembly comprising a cartridge having one end sealed with a pierceable seal and having a stopper adapted to receive a plunger means,

a dosing assembly comprising a plunger means for acting on said stopper, a mechanism for setting a specified dose, and a drive means for advancing said plunger means to deliver the set dose, and

a needle assembly,

a first releasable coupling between the needle assembly and the cartridge assembly, and

a second releasable coupling between the cartridge assembly and the dosing assembly, wherein said first and second releasable couplings are of different types and are selected such that the force applied to couple and decouple said needle assembly to and from said cartridge assembly does not urge said second releasable coupling to disengage, thereby ensuring that said dosing assembly does not move away from said cartridge assembly during coupling and decoupling of said needle assembly, such that said plunger means remains in abutment with said stopper.

31. (Amended) A medication delivery device comprising:

a cartridge assembly comprising a cartridge having one end sealed with a pierceable seal and having a stopper adapted to receive a plunger means,

a dosing assembly comprising a housing and a plunger means movable relative to said housing for acting on said stopper,

a needle assembly,

a first releasable coupling between the needle assembly and the cartridge assembly, and a second releasable coupling between the cartridge assembly and the dosing assembly housing, wherein said first and second releasable couplings are of different types and are selected such that the force applied to couple and decouple said needle assembly to and from said cartridge assembly does not urge said second releasable coupling to disengage, thereby ensuring that the dosing assembly does not move away from the cartridge assembly during coupling and decoupling of said needle assembly, such that said plunger means remains in abutment with said stopper.

REMARKS

Enclosed herewith is a new sheet of formal drawings containing Figs. 2a, 2b, and 3, which is submitted to overcome the objection raised in the Notice of Draftsperson's Patent Drawing Review.

The applicants respectfully request entry of the foregoing amendments to the claims. By the foregoing amendments, the non-elected claims (13-18) would be canceled, along with dependent claims 2-12, 20, and 24. In addition, independent claims 1 and 28 would be amended to overcome the rejection under 35 U.S.C. § 112 (i.e., that it is unclear what the applicant regards as the injection mechanism). As amended, such claims would recite a mechanism for setting a specified dose, e.g., dose setting wheel 9, and a "driving means" for advancing the plunger means (e.g., plunger rod 7). As disclosed in the specification on page 6, the "driving means" includes the actuator button 18 together with any suitable mechanism for advancing the plunger rod element 7 in response to actuating the actuator button 18. Page 6, lines 18-25.

The Examiner objected to the drawings as not showing an "injection mechanism." As noted above, the term "injection mechanism" has been replaced by the term "driving means" for clarity. The drawings expressly show part of a suitable "driving means," in the form of the actuator button 18. Page 6, lines 24-25. Moreover, the specification discloses that the remaining part of the driving mechanism is contained in the dosing assembly housing 17. Page 6, lines 12-25. Thus, element 17

schematically depicts the remaining parts of the "driving means." Because driving mechanisms which advance the plunger rod in response to depressing an actuator button are well known, and because the specification discloses that any suitable driving mechanism may be employed, Page 6, lines 12-25, the applicants respectfully submit that the drawings need only show such mechanism schematically, as the current drawings do. Thus, the applicants respectfully request reconsideration of the objection to the drawings in light of the change in terminology in claims 1 and 28.

By the foregoing amendments, independent claims 1, 28, and 31 would be amended to clarify the function of selecting the first and second couplings in the manner already specified in those claims, in order to point out more clearly the novel features of the claimed invention.

In the device according to claims 1, 28, and 31, a plunger means, such as a rigid or flexible piston rod, pushes a movable stopper in the cartridge barrel in a forward direction in order to administer set doses of medicine. A dose setting mechanism is used to set the size of the dose. When the dose is administered, the piston rod is pushed forward a distance proportional to the set dose, pushing the stopper forward by exactly the same distance. In order to administer accurate doses, it is essential that, between doses, the forward end of the piston rod is not allowed to retract from the stopper. If that were to occur, the initial portion of the piston rod movement, when administering the next dose, would merely close the gap between

the piston rod and the stopper. Because less than the entire movement of the piston rod would push the stopper, a dose smaller than the set dose would be administered.

In conventional durable insulin syringes ("durable" meaning that the cartridge can be replaced), the cartridge assembly is coupled to the dosing assembly by threads. A needle assembly is also removably mounted on the cartridge assembly by threads. The former coupling allows the cartridge (or the entire cartridge assembly, if the cartridge assembly does not contain a separate cartridge holder, such as is shown in Figs. 1-3 of the present application) to be changed when empty. The latter coupling permits the needle to be removed from the device after a dose has been administered, and replaced when a new dose is to be administered.

Because the two threaded couplings are coaxial with one another, if the user grasps the dosing assembly housing when screwing or unscrewing the needle assembly, the cartridge assembly may rotate relative to the dosing assembly housing. If this occurs, the dosing assembly will move, at least by a small distance, in a direction away from the cartridge assembly, causing the piston rod to move axially away from the stopper. And, if the user does not notice such separation, and does not screw the cartridge assembly back into its original, seated position in the dosing assembly, as noted above the next dose administered will be less than the set dose, because the initial segment of the forward movement of the plunger rod will merely close the gap between the plunger rod and the cartridge stopper, rather than push the stopper forward to expel medicine.

The possibility that mounting or removing the needle assembly will cause the plunger to retract from the stopper is eliminated in the device claimed in claims 1, 28, and 31.

As recited in claim 1, the couplings between the needle assembly and cartridge assembly, on the one hand, and between the cartridge assembly and the dosing assembly, on the other hand, are chosen so as to **ensure** that the cartridge assembly does not move away from the dosing assembly during coupling and decoupling of the needle assembly. In other words, such couplings are chosen to ensure that the act of mounting ore removing the needle assembly does not cause the dosing assembly to move in a direction away from the stopper. The limitation in claim 1, that the two couplings must be chosen so that they will inherently **ensure** that such movement between the cartridge assembly and dosing assembly does not occur during needle mounting or removal, ensures that the plunger means will not retract from the stopper during needle mounting and removal.

Claims 28 and 31 recite a preferred structure for ensuring that the plunger will not be retracted from the stopper when changing needles. More particularly, claims 28 and 31 recite that the first and second couplings are different from one another, and further recite that the force applied to couple and decouple the needle assembly will not urge the dosing assembly/cartridge assembly coupling to disengage. In other words, the first and second couplings are chosen such that the force required to disengage the first releasable coupling is in a direction which is

different from the force required to mount or remove the needle assembly. For example, if the first releasable coupling (between the dosing assembly and cartridge assembly) comprises threads, thus requiring a torque about the longitudinal axis to disengage such coupling, the second releasable coupling (for mounting the needle on the cartridge assembly) would not be one which uses a torque about the longitudinal axis to mount and remove the needle.

In the last Office Action, claim 1 was rejected under 35 U.S.C. § 102(b) as being anticipated by Chanoch U.S. patent No. 5,688,251. Claims 28 and 31 were rejected under 35 U.S.C. § 103(a) as being obvious over Chanoch. The Examiner conceded that Chanoch does not disclose the concept of using two different couplings in the same device. However, the Examiner noted that Chanoch discloses that other means for mounting the needle assembly may be used (Col. 8, lines 15-20), and concluded that it would be obvious to modify the releasable couplings of Chanoch to have two different couplings for quicker disconnection. August 24, 2001, Office Action, page 4.

With respect to the anticipation rejection of claim 1, in Chanoch, both couplings are shown as concentric threaded couplings. Therefore, a risk exists that the dosing assembly can be partly unscrewed from the cartridge assembly if the user grasps the dosing assembly housing instead of the cartridge assembly when screwing or unscrewing the needle. Thus, the example disclosed in Chanoch does not have a pair of couplings that will ensure that the dosing assembly will not move away

slightly, i.e., partially separate, from cartridge assembly when the needle is screwed onto or off of the cartridge assembly, as recited in claim 1.

Although Chanoch discloses that alternate couplings can be used to mount the needle assembly on the cartridge assembly, there is no suggestion that, if a different type of coupling type is to be employed to mount the needle, it should be selected to ensure that the force applied in mounting or removing the needle cannot cause the dosing assembly to move away from the cartridge assembly, as recited in claim 1. In other words, Chanoch fails to disclose that the alternative coupling for the needle assembly should be chosen to prevent any possibility that the dosing assembly could rotate relative to the cartridge assembly, and thereby partially unscrew from the cartridge assembly, during needle mounting/removal.

To support a finding of anticipation, a reference must expressly or at least inherently disclose every element of the claim. Continental Can Co. USA v. Monsanto Co., 948 F.2d 1264, 1268, 20 U.S.P.Q.2d 1746, 1749 (Fed. Cir. 1991). Moreover, in order for a disclosure to be "inherent," the missing descriptive matter must necessarily be present in the prior art reference such that one skilled in the art would recognize such a disclosure. *Id.* In the case of Chanoch, if a different type of coupling were to be chosen for the needle assembly, it would not necessarily ensure that movement between the doser assembly and cartridge assembly, and consequently between the plunger and stopper, is prevented. Because the features recited in claim 1 would necessarily be present if an alternative coupling were to be used for the needle

assembly, the applicants respectfully submit that Chanoch does not anticipate claim 1.

Because amended claim 1 is not anticipated by Chanoch (and, for reasons discussed below in connection with claims 28 and 31, the features recited in claim 1 are not obvious), the applicants respectfully request allowance of such claim.

With respect to the obviousness rejection of claims 28 and 31, which recite specifically that the coupling pair must be chosen such that the force of mounting or removing the needle will not urge the cartridge assembly/dosing assembly coupling to disengage, the exemplary embodiment in Chanoch does not provide a combination of couplings wherein screwing the needle onto or off of the cartridge assembly will not urge the other coupling to disengage, as recited in claims 28 and 31. In Chanoch, if the user grasps the dosing housing while screwing the needle onto the cartridge assembly housing or unscrewing the needle from such housing, such twisting force will be transmitted across the cartridge assembly/dosing assembly threaded coupling. In one of the two rotational directions, i.e., either screwing the needle on or unscrewing the needle, such twisting force will urge the cartridge assembly to unscrew from the dosing assembly (even if no separation of the two syringe parts actually results).

Although, as the Examiner notes, Chanoch discloses that other couplings can be used for the needle assembly, Chanoch contains no suggestion to select an alternative coupling for the needle assembly such that the force applied in

mounting or removing the needle will be in a direction that will not urge the coupling between the dosing assembly and cartridge assembly to disengage, as recited in claims 28 and 31.

Applicant's disclosure of selecting two couplings that do not interact with one another, i.e., where the actuation of one will never cause actuation of the other, is obvious only in hindsight. While it is true that, if a person skilled in the art were to try different couplings for the needle assembly as suggested in Chanoch, such person might discover that pairing certain couplings produces the benefits of the invention recited in claims 1, 28, and 31, it is well settled that "obvious to try" is an improper standard for determining obviousness. In re Deuel, 51 F.3d 1552, 1559, 34 U.S.P.Q.2d 1210, 1216 (Fed. Cir. 1995).

The conclusion that the invention claimed in claims 1, 28, and 31 is not obvious, except in hindsight, can no better be illustrated than by the fact that, while Chanoch discloses that other needle couplings can be employed, the only embodiment disclosed in Chanoch (i.e., the most preferable embodiment known to Chanoch) utilizes couplings where screwing and unscrewing the needle can cause the dosing assembly/cartridge assembly coupling to partly disengage. Thus, the invention claimed in claims 1, 28, and 31 was not obvious to Chanoch.

The applicants urge the entry of such language changes in claims 28, and 31, insofar as the Examiner already appears to interpret claims 28 and 31 in such a manner. With respect to claim 1, prior to amendment, such claim recited that the

choice of couplings "secure" that the plunger abuts the stopper when the needle is mounted or removed. The term "secure" has been changed to "ensure" for idiomatic reasons, and insofar as the Examiner, in rejecting claim 1 based on anticipation, appears to have given the phrase "secure . . . " no weight. The language revisions thus do not change the scope of the existing claims, and for such reasons entry is respectfully requested.

Finally, the applicants note that claims 1 and 28 would be amended to change the term "selected dose" to "set dose" for clarity, insofar as those claims refer previously to "setting" a dose rather than "selecting" a dose. Such amendment is thus merely of form, to conform the language used in the claim, and does not affect the scope of the claim.

For the reasons discussed above, entry of the proposed amendments, and favorable reconsideration and allowance of the application, are respectfully requested.

Respectfully submitted,

Robert B. Smith

Robert B. Smith
PTO Registration No. 28,538
Attorney for applicant(s)

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(212) 735-3020

VERSION WITH MARKINGS TO SHOW CHANGES MADE

CHANGES IN THE AMENDED CLAIMS

1. (Twice Amended) A medication delivery device comprising:

a cartridge assembly having a distal end and a proximal end, said distal end of the cartridge assembly comprising coupling means for releasably mounting a needle assembly, and said cartridge assembly comprising a cartridge having one end sealed with a pierceable seal and having a stopper adapted to receive a plunger means,

a dosing assembly comprising a plunger means for acting on said stopper, a [and a dose-setting and injection] mechanism for setting a specified dose, and [for driving] a driving means for advancing said plunger means to deliver the [selected] set dose, and

a needle assembly including a coupling means for engaging the coupling means of said cartridge assembly to form a releasable coupling between said needle assembly and said cartridge assembly,

wherein the cartridge assembly and the dosing assembly are releasably coupled together, and wherein the combination of couplings between the dosing assembly and the cartridge assembly, and between the needle assembly and the cartridge assembly, respectively, is selected to [secure] ensure that the force applied to couple and decouple said needle assembly to and from said cartridge assembly

does not cause said dosing assembly to move away from said cartridge assembly during coupling and decoupling of said needle assembly, such that said [the] plunger means [abuts on] remains in abutment with said [the] stopper during such coupling and decoupling [of the needle assembly].

21. (Amended) A medication delivery device according to claim [20] 1, wherein the dosing assembly is released from the cartridge assembly through a movement including an axial movement.

25. (Amended) A medication delivery device according to claim 1, wherein the cartridge assembly comprises a housing for receiving a cartridge.

28. (Amended) A medication delivery device comprising:

a cartridge assembly comprising a cartridge having one end sealed with a pierceable seal and having a stopper adapted to receive a plunger means,

a dosing assembly comprising a plunger means for acting on said stopper, a [and a dose-setting and injection] mechanism for setting a specified dose, and [for driving] a drive means for advancing said plunger means to deliver the [selected] set dose, and

a needle assembly,

a first releasable coupling between the needle assembly and the cartridge assembly, and

a second releasable coupling between the cartridge assembly and the dosing assembly, wherein said first and second releasable couplings are of different

types and are selected such that the force applied to couple and decouple [releasing or attaching] said needle assembly [onto] to and from said cartridge assembly does not urge said second releasable coupling to disengage, thereby ensuring that said dosing assembly does not move away from said cartridge assembly during coupling and decoupling of said needle assembly, such that said plunger means remains in abutment with said stopper.

31. (Amended) A medication delivery device comprising:

a cartridge assembly comprising a cartridge having one end sealed with a pierceable seal and having a stopper adapted to receive a plunger means,

a dosing assembly comprising a housing and a plunger means movable relative to said housing for acting on said stopper,

a needle assembly,

a first releasable coupling between the needle assembly and the cartridge assembly, and a second releasable coupling between the cartridge assembly and the dosing assembly housing, wherein said first and second releasable couplings are of different types and are selected such that the force applied to couple and decouple [releasing or attaching] said needle assembly [onto] to and from said cartridge assembly does not urge said second releasable coupling to disengage, thereby ensuring that the dosing assembly does not move away from the cartridge assembly during coupling and decoupling of said needle assembly, such that said plunger means remains in abutment with said stopper.

EXHIBIT 4

3763

Attorney Docket No.: 5533.200-US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Buch-Rasmussen et al.

Serial No.: 09/349,748

Group Art Unit: 3763

Filed: July 8, 1999

Examiner: K. Simmons

Confirmation No: 7085

For: Medical Device

CERTIFICATE OF MAILING UNDER 37 CFR 1.8(a)

Commissioner for Patents
Washington, DC 20231

Sir:

I hereby certify that the attached correspondence comprising:

1. Amendment No Fee Transmittal
2. Amendment

is being deposited with the United States Postal Service as first class mail in an envelope addressed to:

Commissioner for Patents
Washington, DC 20231

on August 15, 2002.

Tracy Bronner
(name of person mailing paper)

Tracy Bronner
(signature of person mailing paper)

Attorney Docket No.: 5533.200-US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Buch-Rasmussen et al.

Serial No.: 09/349,748

Group Art Unit: 3763

Filed: July 8, 1999

Examiner: K. Sirmons

Confirmation No: 7085

For: Medical Device

AMENDMENT NO FEE TRANSMITTAL

Commissioner for Patents
Washington, DC 20231

Sir:

Transmitted herewith is an Amendment for the above-identified application.

No fee extension fee is required for this Amendment as it is being submitted within the shortened statutory reply period. Please charge any and all additional fees that may due in connection with this paper or application, including the fee for the additional independent claim added by this amendment, estimated to be $84, to Novo Nordisk of North America, Inc., Deposit Account No. 14-1447. A duplicate of this authorization is attached.

Respectfully submitted,

Date: August 15, 2002

Marc A. Began Reg. No. 48,829
Novo Nordisk of North America, Inc.
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(212) 867-0123

Attorney Docket No.: 5533.200-US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Buch-Rasmussen et al.

Application No.: 09/349,748 Group Art Unit: 3763

Filed: February 11, 2002 Examiner: K. Sirmons

For: Medical Device

AMENDMENT UNDER 37 C.F.R. 1.111

Commissioner for Patents
Washington, DC 20231

Sir:

In response to the Office Action mailed May 15, 2002, please amend the above-captioned application as follows (a marked up version pursuant to 37 C.F.R. 1.21 is attached hereto, where applicable):

IN THE CLAIMS:

Please cancel claims 1-13 and 19-33 without prejudice or disclaimer.

Please add new claims 34-48 as shown below:

34. A medication delivery device comprising:

a cartridge assembly comprising a cartridge having a pierceable seal at one end and a moveable stopper at an opposite end;

a dosage assembly comprising a plunger means for acting on the stopper; a mechanism for setting a specified dose; and a drive means for advancing the plunger means to deliver the specified dose;

a needle assembly;

a first coupling means for coupling and uncoupling the needle assembly to and from the cartridge assembly;

a second coupling means for coupling and uncoupling the cartridge assembly to and from the dosage assembly;

wherein the first and second coupling means are selected such that when a user grasps the needle assembly and applies a force to couple it to and to uncouple it from the cartridge assembly, while simultaneously grasping the dosage assembly and applying an equal but opposite force thereto, the cartridge assembly cannot not move axially with respect to the dosage assembly.

35. The medication delivery device of claim 34, wherein the first coupling means comprises a means for coupling or uncoupling the needle assembly through an axial movement of the needle assembly relative to the cartridge assembly and the second means comprises a threaded means.

36. The medication delivery device of claim 35, wherein the cartridge assembly comprises a housing for receiving the cartridge and wherein the first coupling means comprises a snap lock and wherein the snap lock is an integral part of the needle assembly.

37. A medication delivery device upon which a needle assembly can be mounted, the device comprising:

a cartridge assembly comprising a cartridge having a movable stopper at one end and a pierceable seal at an opposite end;

a dosage assembly comprising a mechanism for setting a specified dose, a plunger means for abutting the moveable stopper, and a drive means for driving the plunger means to deliver the set doseage;

a first coupling means for coupling and uncoupling the cartridge assembly to and from the dosage assembly; and

a second coupling means for coupling and uncoupling a needle assembly to and from the cartridge assembly;

wherein the first and second coupling means are selected so that when a user grasps the needle assembly and applies force to the needle assembly to couple and uncouple it

from the device while simultaneously grasping the dosage assembly and applying a equal and opposite force to the dosage assembly, the dosage assembly cannot move relative to the cartridge assembly, thereby ensuring that the plunger means remains abutted against the stopper.

38. The medication delivery device recited in claim 37, wherein the second coupling means comprises a threaded coupling means and wherein the second coupling means comprises a means for coupling and uncoupling through an axial movement of the needle assembly relative to the cartridge assembly.

39. The medication delivery device of claim 37, wherein the first coupling means comprises a means for uncoupling through an axial movement of the cartridge assembly relative to the dosing assembly.

40. The medication delivery device of claim 37, wherein the first coupling means comprises a threaded coupling means.

41. The medication delivery device of claim 37, wherein the cartridge assembly comprises a housing to accommodate the cartridge and wherein the second coupling means comprises a means for axially coupling or uncoupling the needle assembly from the cartridge assembly.

42. The medication delivery device of claim 37, wherein the second coupling means comprises a threaded coupling means.

43. A medication delivery device comprising:

a cartridge assembly comprising:

a housing capable of housing a removable cartridge that has a pierceable seal at one end, is filled with medication, and has a moveable stopper at an opposite end that when moved toward the medication pressurizes the medication; and

a needle mounting means for mounting a needle on the cartridge assembly;

a dosage assembly for delivering a set dose of medication, comprising:

a plunger means for moving the stopper, a dose setting means for setting a dose, and a drive means for driving the plunger means to deliver the set dose, wherein after a portion of medication is expelled from the cartridge, the plunger means abuts the stopper;

a first means for coupling and uncoupling a needle assembly to and from the cartridge assembly; and

a second means for coupling and uncoupling the dosage assembly to and from the cartridge assembly,

wherein the first and second coupling means are chosen so that when a user simultaneously grasps the dosage assembly and the needle assembly and applies a force to the needle assembly to couple (or uncouple) the needle to or from the device the cartridge assembly is positively precluded from moving axially relative to the cartridge assembly.

44 A medication delivery device comprising:

a cartridge assembly for housing a removable cartridge containing a medication;

a needle assembly;

a dosage assembly comprising a mechanism for setting a dosage less than the full amount of medication contained in the cartridge;

a first coupling means for coupling and uncoupling the needle to and from a removable cartridge housed in the cartridge assembly; and

a second coupling means for coupling and uncoupling the cartridge assembly to and from the dosage assembly;

wherein the first and second coupling means are chosen so that when a user couples or uncouples the needle assembly from the cartridge by grasping the needle assembly and the dosage assembly simultaneously and applying force to both, the second coupling

means prevents axial movement of the cartridge assembly relative to the dosage assembly.

45. The medication delivery device of claim 44, wherein the dosage assembly comprises a plunger means and a drive means and wherein the second coupling means is selected to ensure that uncoupling of the needle assembly from the dosage assembly does not result in movement of the plunger means relative to a removable cartridge that is housed in the cartridge assembly.

46. The medication delivery device of claim 45, wherein the first coupling means comprises a snap-lock means for allowing axial coupling and uncoupling of the needle assembly to and from the cartridge assembly without the need to rotate the needle assembly relative to the dosage assembly.

47. The medication delivery decide of claim 46, wherein the second coupling means comprises a threaded coupling and wherein the first coupling means is at least partially integrated into the needle assembly.

48. The medication delivery device of claim 47, wherein the snap lock means is fully integrated into the needle assembly.

REMARKS

Claims 1-13 and 19-33 have been canceled without prejudice or disclaimer. Claims 34-48 have been added and therefore are pending in the present application. Claims 34-48 are supported by the drawings, the original claims, and the specification.

It is respectfully submitted that the present amendment presents no new matter and places this case in condition for allowance. Reconsideration of the application in view of the above amendments and the following remarks is requested.

In the previous office action, the Examiner rejected claims 1, 19, 21-23 and 25-27 under 35 USC § 102(b) in view of Chanoch US Pat. No. 5,688,251 and rejected claims 28-33 under 35 USC § 103(a) in view of Chanoch. The Examiner dismissed the Applicants' previous arguments that their invention is novel and non-obvious because Chanoch does not disclose selection of a means for securing the needle to cartridge assembly and a means for securing the dosing assembly to the cartridge assembly such that the dosing assembly does not move relative to the cartridge assembly during removal or attachment of a needle. The Examiner has, ostensibly, taken the position that one of ordinary skill in the art would grasp the Chanoch cartridge assembly or both the Chancoch cartridge assembly and the Chanoch dosing assembly when removing or attaching a needle and therefore the dosing assembly would not move relative to the cartridge assembly during a needle change. The Examiner, also asserts that because Chanoch states that other means for mounting the needle cannula to the cartridge holder may be provided, it discloses that two different types of coupling means on a single device or that something other than threads as shown in the figures may be used.

Applicants note that even if the Examiner's view of Chanoch is correct, Chanoch does not disclose or even suggest a means for ensuring that the dosing assembly does not move relative to the cartridge assembly when the dosing assembly and the needle are intentionally grasped during a needle change. Chanoch is silent as to how and what criteria should be used when selecting a means for securing the needle assembly to the cartridge assembly and the cartridge assembly to the dosing assembly. Moreover, Chanoch fails to disclose or even suggest that the two securing means should be chosen so that when force is applied to remove (or attach) the needle while the

dosage assembly is grasped, the security of the dosage assembly to the cartridge assembly is not jeopardized.

As presently claimed in the new pending claims (i.e., claims 34-48), Applicants' invention specifically requires that the means for securing the needle to the cartridge assembly and the means for securing the cartridge assembly to the dosing assembly be chosen so that when the needle assembly and the dosing assembly are grasped and a force applied to both to remove (or attach) the needle assembly, the cartridge assembly remains securely fixed to the dosing assembly. Thus, it is irrelevant to the patentability of the present claims whether one would grasp the cartridge assembly during a needle change. By their own terms, the claims now require that when the dosing assembly and needle assembly are grasped during needle attachment or removal, the means for securing the dosing assembly to the cartridge assembly must prevent unintended axial movement of the dosage assembly relative to the cartridge assembly. By preventing the cartridge assembly from moving relative to the dosing assembly when changing a needle the accuracy of a subsequently administered dose can be guaranteed.

Conclusion

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to

contact the undersigned by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,

Date: August 15, 2002

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405 Lexington Avenue, Suite 6400
New York, NY 10174-6401
(212) 867-0123

EXHIBIT 5

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/349,748	07/08/1999	THOMAS BUCH-RASMUSSEN	5533.200-US	7085

26137 7590 05/15/2002

PATENT DEPARTMENT
SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP
FOUR TIMES SQUARE
NEW YORK, NY 10036

EXAMINER	
SIRMONS, KEVIN C	

ART UNIT	PAPER NUMBER
3763	

DATE MAILED: 05/15/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 07-01)

11 K

Notice of Allowability	Application No. 09/349,748	Applicant(s) BUCH-RASMUSSEN ET AL.
	Examiner Kevin C. Simmons	Art Unit 3763

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address*--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 1/22/02.
2. ☒ The allowed claim(s) is/are 1-11.
3. ☒ The drawings filed on 1/9/02 are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☒ None of the:
   1. ☒ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____.
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.
5. ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
   (a) ☐ The translation of the foreign language provisional application has been received.
6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

8. ☐ CORRECTED DRAWINGS must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
   1) ☐ hereto or 2) ☐ to Paper No. _____.
   (b) ☐ including changes required by the proposed drawing correction filed _____, which has been approved by the Examiner.
   (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the top margin (not the back) of each sheet. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1☐ Notice of References Cited (PTO-892)
3☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
5☐ Information Disclosure Statements (PTO-1449), Paper No. _____.
7☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
2☐ Notice of Informal Patent Application (PTO-152)
4☐ Interview Summary (PTO-413), Paper No. _____.
6☐ Examiner's Amendment/Comment
8☒ Examiner's Statement of Reasons for Allowance
9☐ Other

DETAILED ACTION

Allowable Subject Matter

Claims 34-44 are allowable over the prior art of record at the time the invention was made.

The following is an examiner's statement of reasons for allowance: Claims 34, 37, 43 and 44 are allowable over the prior art of record because the prior art does not disclose or render obvious the combination of a first or second coupling means which comprises a snap lock for assisting in coupling or uncoupling of a needle assembly from a cartridge by grasping the needle assembly and the dosage assembly simultaneously and applying force to both, thus preventing the cartridge assembly from moving axially with respect to the dosage assembly.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Kevin C. Sirmons whose telephone number is (703) 306-5410. The examiner can normally be reached on Monday - Thursday from 6:30 am to 4:00 pm. The examiner can also be reached on alternate Fridays.

Kevin C. Sirmons
Patent Examiner
1/23/03

BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

EXHIBIT 6

US005688251A

United States Patent [19]

Chanoch

[11] Patent Number: 5,688,251

[45] Date of Patent: Nov. 18, 1997

[54] **CARTRIDGE LOADING AND PRIMING MECHANISM FOR A PEN INJECTOR**

[75] Inventor: **Lawrence H. Chanoch**, Mahwah, N.J.

[73] Assignee: **Becton Dickinson and Company**, Franklin Lakes, N.J.

[21] Appl. No.: **530,527**

[22] Filed: **Sep. 19, 1995**

[51] **Int. Cl.**[6] **A61M 5/00**

[52] **U.S. Cl.** **604/208**; 604/186; 604/187; 604/232; 222/46; 222/309

[58] **Field of Search** 604/110, 186, 604/187, 188, 192, 195, 196, 221, 207–211, 232, 71, 72, 218, 224, 234; 222/46, 48, 309

[56] **References Cited**

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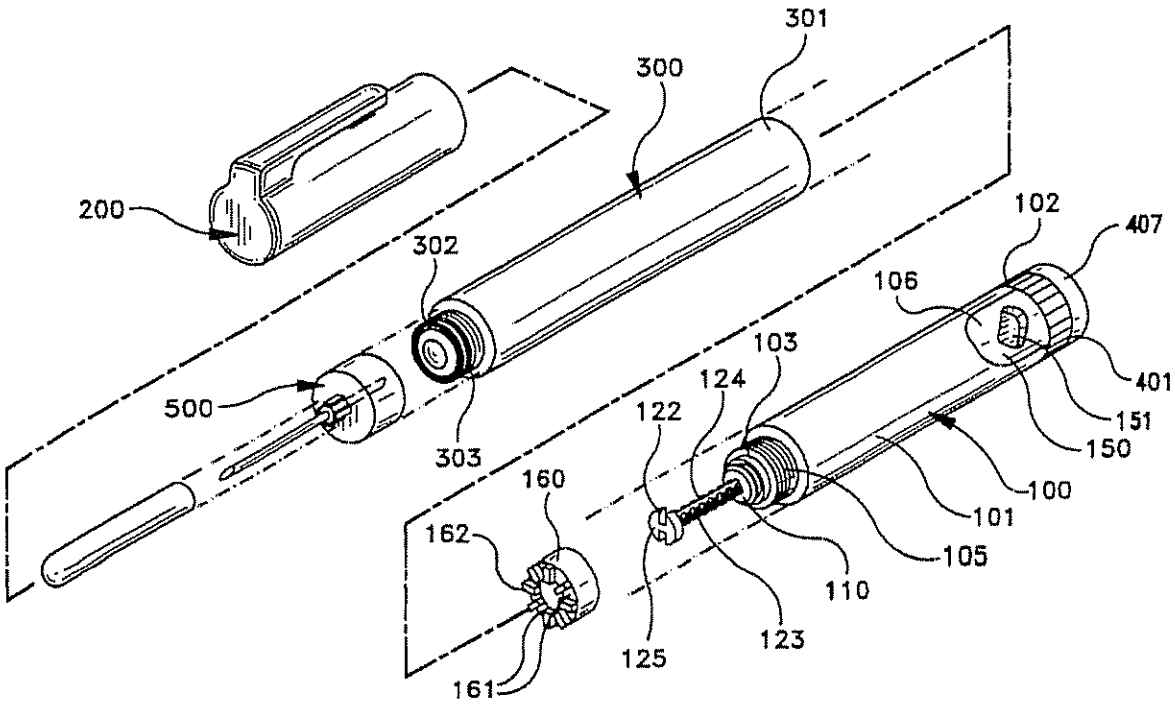
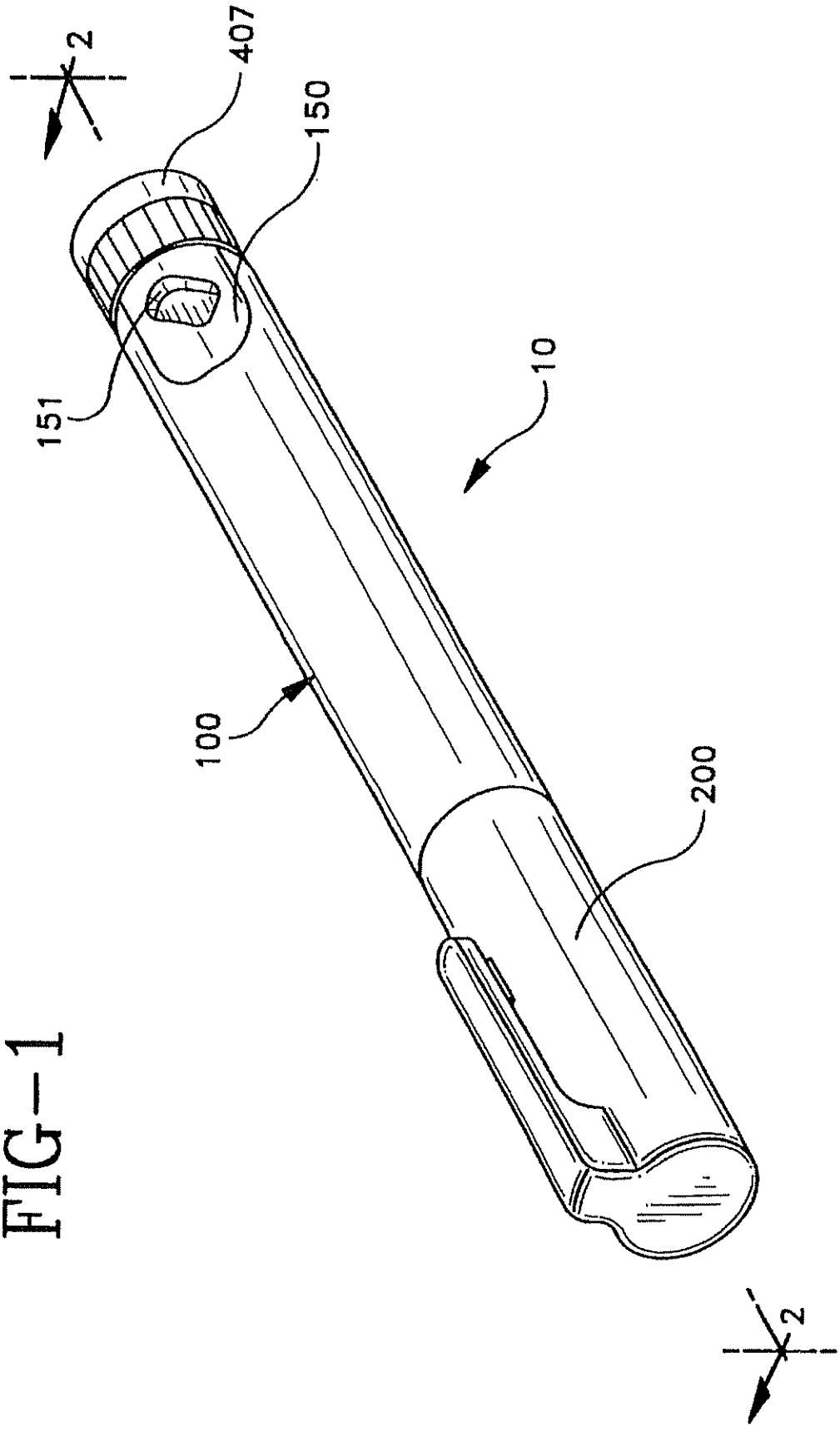
Primary Examiner—Corrine M. McDermott
Assistant Examiner—Cris L. Rodriguez
Attorney, Agent, or Firm—Alan W. Fiedler

[57] **ABSTRACT**

A medication delivery pen is provided having a medication cartridge holder assembly, a pen body assembly and a cap. The reusable pen body assembly includes an improved loading and priming mechanism that allows the user to easily load a new cartridge and prime the pen without having to manually manipulate the pen's lead screw and related driving components.

9 Claims, 5 Drawing Sheets





FIG—1

FIG-2

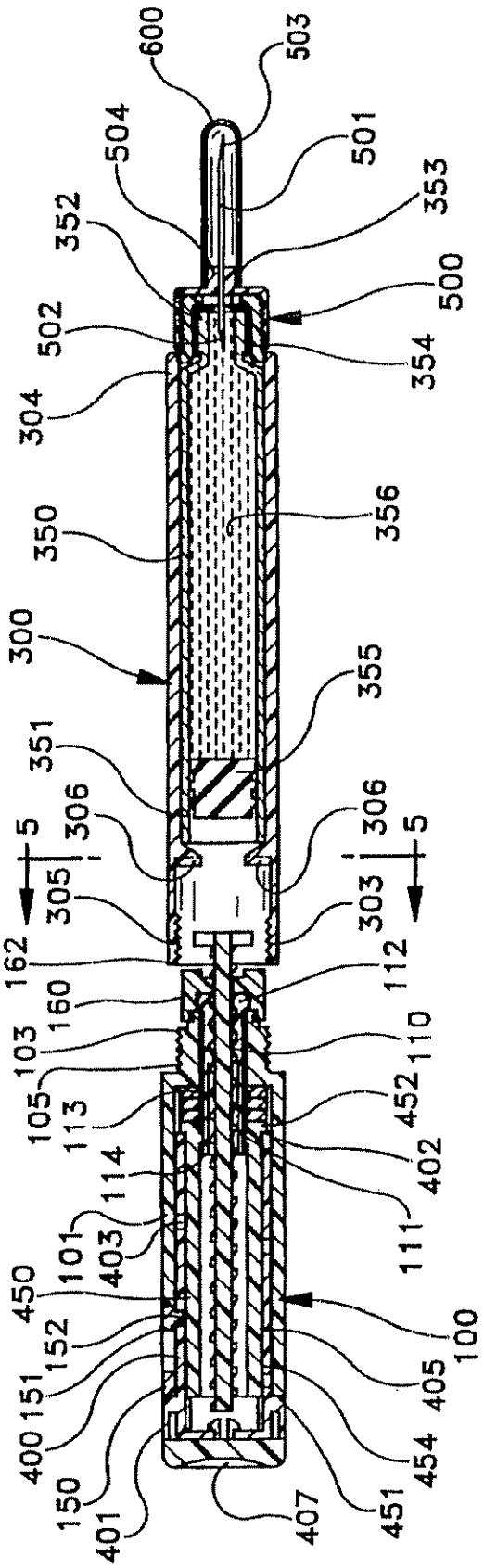

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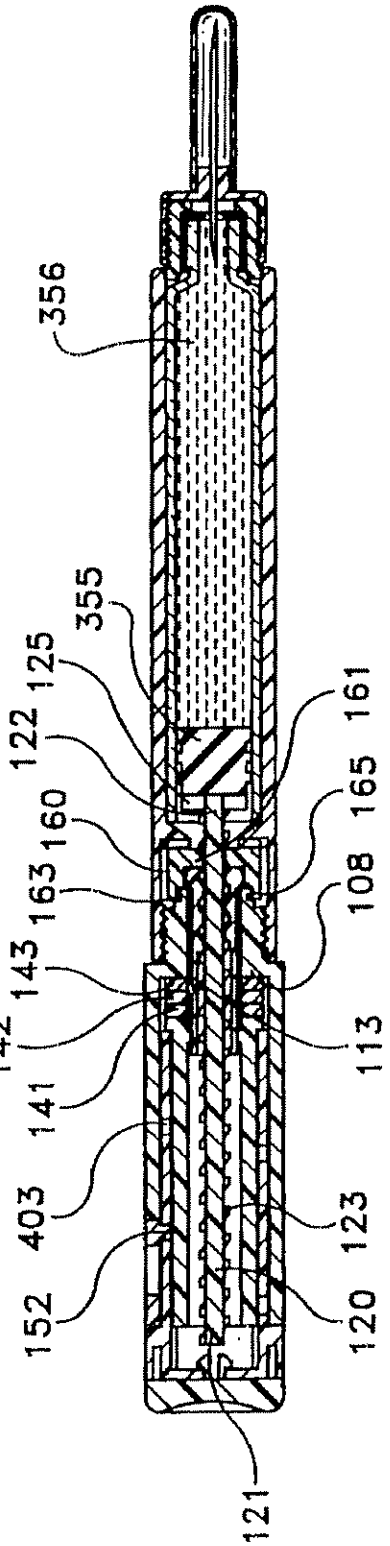
FIG-3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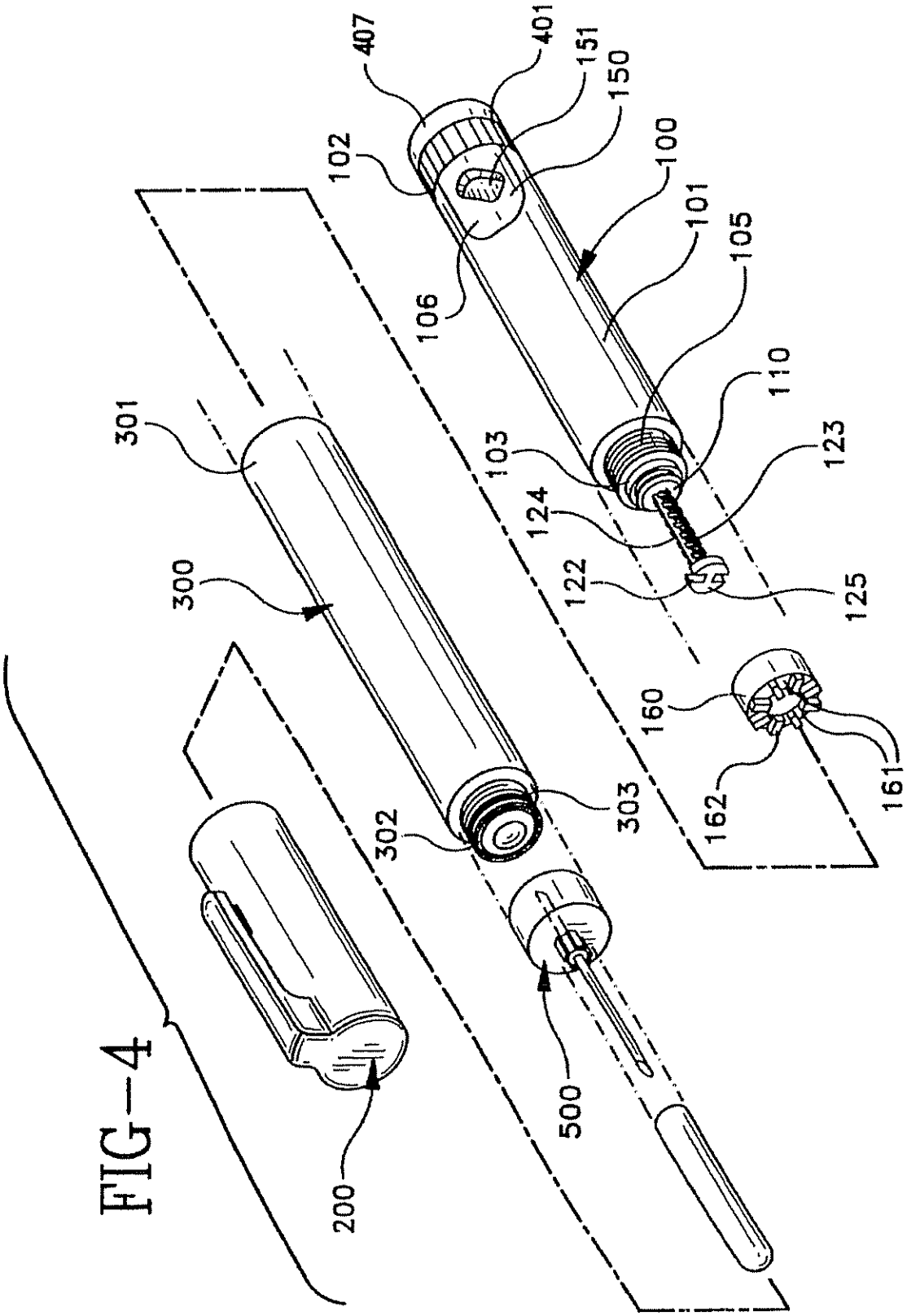
407
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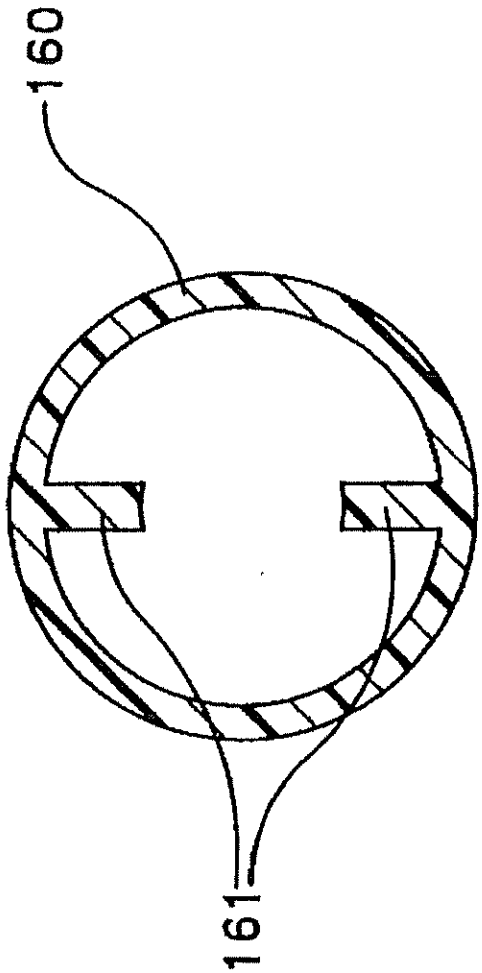
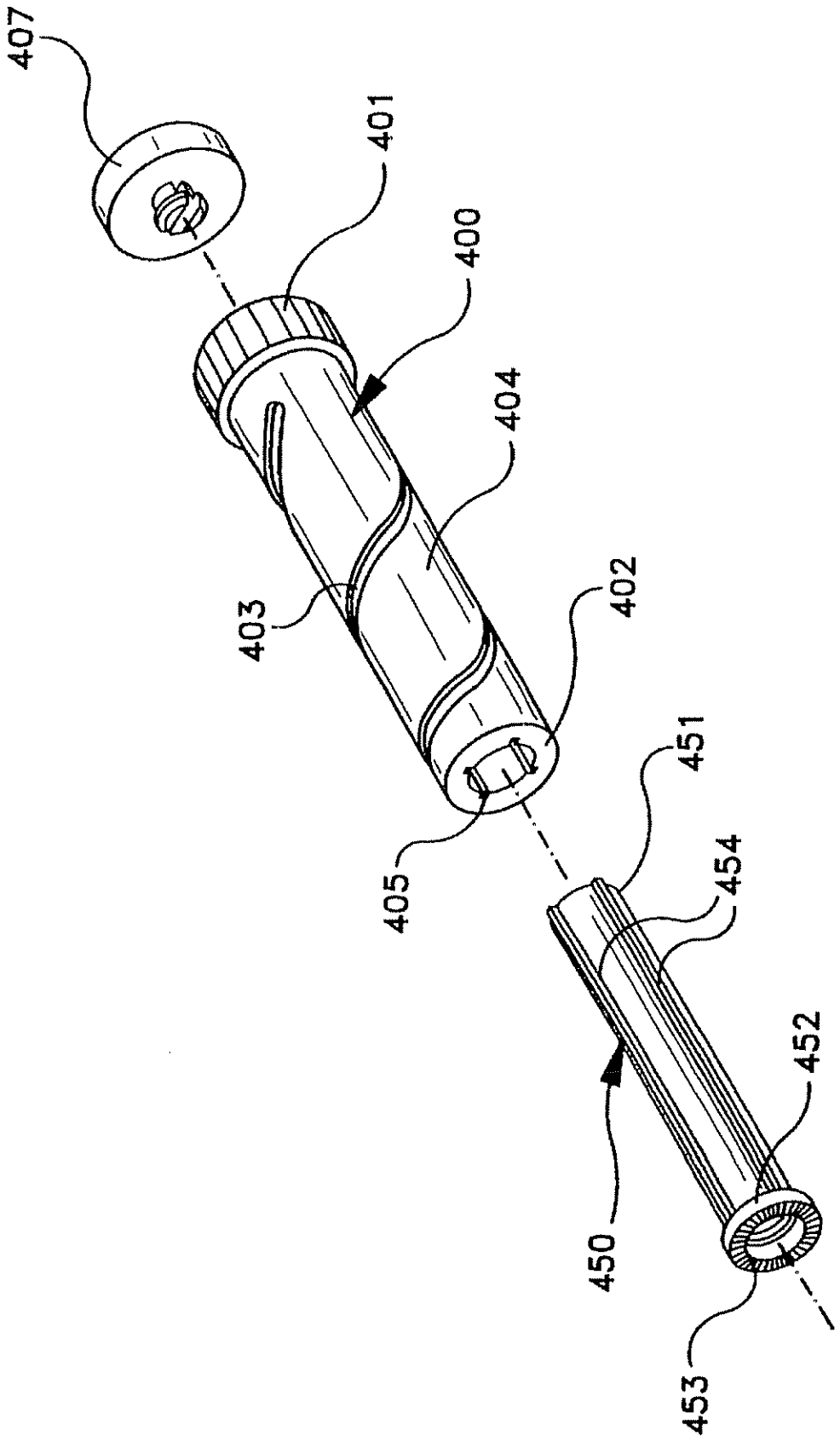
FIG—4



FIG—5



FIG—6

CARTRIDGE LOADING AND PRIMING MECHANISM FOR A PEN INJECTOR

BACKGROUND OF THE INVENTION

1. Field of the Invention

The subject invention relates to an improved cartridge loading and priming mechanism for a medication delivery pen having a cartridge holder assembly and a pen body assembly removably mounted to the cartridge holder assembly for delivering selected doses of medication.

2. Description of Related Art

Hypodermic syringes are used to deliver selected doses of medication to patients. The prior art hypodermic syringe includes a syringe barrel having opposed proximal and distal ends. A cylindrical chamber wall extends between the ends and defines a fluid receiving chamber. The proximal end of the prior art syringe barrel is substantially open and receives a plunger in sliding fluid tight engagement. The distal end of the prior art syringe barrel includes a passage communicating with the chamber. A needle cannula is mounted to the distal end of the prior art syringe barrel, such that the lumen of the needle cannula communicates with the passage and the chamber of the syringe barrel. Movement of the plunger in a proximal direction draws fluid through the lumen of the needle cannula and into the chamber. Movement of the plunger in a proximal-to-distal direction urges fluid from the chamber and through the lumen of the needle cannula.

Medication to be injected with the prior art hypodermic syringe often is stored in a vial having a pierceable elastomeric seal and accessed by piercing the elastomeric seal with the needle cannula. A selected dose of the medication may be drawn into the chamber of the syringe barrel by moving the plunger a selected distance in a proximal direction. The needle cannula is withdrawn from the vial, and the medication is injected into a patient by moving the plunger in a distal direction.

Some medication, such as insulin is self-administered. The typical diabetes patient will require injections of insulin several times during the course of the day. The required dose of insulin will vary from patient to patient, and for each patient may vary during the course of the day and from day to day. Each diabetes patient will establish a regimen that is appropriate for his or her own medical condition and for his or her lifestyle. The regimen typically includes some combination of a slow or medium acting insulin and a faster acting insulin. Each of these regimens may require the diabetes patient to periodically self-administer insulin in public locations, such as places of employment or restaurants. The required manipulation of the standard prior art hypodermic syringe and vial can be inconvenient and embarrassing in these public environments.

Medication delivery pens have been developed to facilitate the self-administration of medication. One prior art medication delivery pen includes a vial holder into which a vial of insulin or other medication may be received. The vial holder is an elongate generally tubular structure with proximal and distal ends. The distal end of the prior art vial holder includes mounting means for engaging a double-ended needle cannula. The proximal end also includes mounting means for engaging a driver and dose setting apparatus as explained further below. A disposable vial for use with the prior art vial holder includes a distal end having a pierceable elastomeric seal that can be pierced by one end of a double-ended needle cannula. The proximal end of this prior art vial includes a plunger slidably disposed in fluid tight engagement with the cylindrical wall of the vial. This prior art medication delivery pen is used by inserting the vial of medication into the vial holder. A prior art pen body then is connected to the proximal end of the vial holder. The pen body includes a dose setting apparatus for designating a dose of medication to be delivered by the pen and a driving apparatus for urging the plunger of the vial distally for a distance corresponding to the selected dose.

The user of the pen mounts a prior art double-ended needle cannula to the distal end of the vial holder such that the proximal point of the needle cannula pierces the elastomeric seal on the vial. The patient then selects a dose and operates the pen to urge the plunger distally to deliver the selected dose. The dose selecting apparatus returns to zero upon injection of the selected dose with this prior art medication delivery pen. The patient then removes and discards the needle cannula, and keeps the prior art medication delivery pen in a convenient location for the next required medication administration. The medication in the vial will become exhausted after several such administrations of medication. The patient then separates the vial holder from the pen body. The empty vial may then be removed and discarded. A new vial can be inserted into the vial holder, and the vial holder and pen body can be reassembled and used as explained above.

The above described reusable medication delivery pen is effective and much more convenient for self-administration of medication than the typical hypodermic syringe and separate medication vial. However, the disassembly of the pen to remove empty medication vials and to insert new ones is an inconvenience. As a result, disposable pens have been developed. The prior art disposable medication delivery pen includes a vial of insulin or other such medication permanently encapsulated therein. The patient need merely connect a double-ended needle cannula to the disposable pen for each administration of medication. The prior art disposable pen can be discarded when the supply of medication permanently encapsulated therein has been exhausted.

Disposable medication delivery pens offer certain conveniences to the patient who is required to self-administer medication. However, the dose selecting and driving mechanisms of prior art medication delivery pens are fairy complex devices and costly to manufacture. Hence, a substantial cost penalty is associated with the convenience of using a disposable medication delivery pen.

Another problem with the above-described medication delivery pens is in loading and priming the penis. These pens usually utilize a lead screw and matching nut combination that translate a rotary dose setting motion into a linear lead screw motion required to expel medication from the pen or cartridge. In such a mechanism, the nut is allowed to rotate during medication delivery while rotation of the lead screw is prevented by means of a rigidly mounted ring with tabs extending into the lead screw. Therefore, as the nut turns the pre-selected amount, threads on the nut and lead screw cause the lead screw to move axially to deliver the medication. Then, when the cartridge is empty and must be replaced, the fully extended lead screw must be manually rotated and returned to a starting position to receive a new cartridge. However, manual rotation of the lead screw is very difficult since the tabbed ring is intended to prevent rotation of the lead screw.

SUMMARY OF THE INVENTION

It is an objective of the present invention to overcome the problem with moving the lead screw back into the pen during cartridge loading found in prior art pens by providing

a medication delivery pen having an improved cartridge loading and priming mechanism that allows a patient to easily load and prime the pen. The present invention provides a pen with a lead screw that is easily slid back into the pen during cartridge loading and thereby eliminates the need for a patient to manipulate an anti-rotation tabbed ring. In the present invention the lead screw does not stop sliding until the cartridge holder assembly has been fully threaded onto the pen housing and, therefore, provides automatic priming of the pen during the threading operation and causes the lead screw to automatically engage with a drive mechanism.

In particular, the medication delivery pen of the present invention includes a medication cartridge holder assembly that is selectively engageable with and disengageable from a pen body assembly. In particular, the medication delivery pen includes means for allowing the lead screw in the medication delivery pen to automatically and easily slide into and prime the medication delivery pen as the cartridge assembly approaches the pen body assembly, when the lead screw is in contact with the plunger in the cartridge. The medication pen also includes means for engaging the lead screw to the cartridge holder assembly as the cartridge is being threaded to the pen body assembly and means for engaging the lead screw to the drive mechanism when the cartridge holder assembly has been fully threaded to the pen body assembly.

These and other aspects, features and advantages of the present invention will become apparent from the following detailed description taken in conjunction with the accompanying drawings.

DESCRIPTION OF THE DRAWINGS

FIG. **1** is a perspective view of the medication delivery pen of the subject invention;

FIG. **2** is a longitudinal cross-sectional view of an unassembled medication delivery pen shown in FIG. **1** along lines **2—2**;

FIG. **3** is a longitudinal cross-sectional view of an assembled medication delivery pen shown in FIG. **2**;

FIG. **4** is a exploded perspective view of the medication delivery pen shown in FIG. **1**;

FIG. **5** is a cross-sectional view of the medication delivery pen shown in FIG. **2** along lines **5—5**; and FIG. **6** is a further exploded perspective view of dose knob **400** and driver **450**, shown in FIG. **2**.

DETAILED DESCRIPTION

A medication delivery pen in accordance with the subject invention is identified generally by the numeral **10** in FIGS. **1–4**. Medication delivery pen **10**, as shown in FIGS. **1–4**, includes a reusable pen body assembly **100**, a cap **200**, a cartridge holder assembly **300**, and a needle cannula assembly **500**. Cartridge holder assembly **300** includes opposed proximal and distal ends **301** and **302**, respectively. Proximal end **301** of cartridge holder assembly **300** is dimensioned and configured to threadedly engage pen body assembly **100**, as explained further herein. Distal end **302** of cartridge holder assembly **300** is configured to securely but releasably engage needle cannula assembly **500**.

The preferred embodiment of reusable pen body assembly **100** is illustrated in detail in FIGS. **2–4**. It is understood, however, that variations from this preferred embodiment may be provided, and are considered to be within the scope of the subject invention. Reusable pen body assembly **100** includes a cylindrical housing **101** having opposed proximal and distal ends **102** and **103**. An array of external threads **105** extends proximally from distal end **103** for threaded engagement with threads **303** in proximal end **301** of cartridge holder assembly **300**. Portions of housing **101** adjacent distal end **103** are characterized by an army of clutch teeth (not shown) molded therein. Proximal end **102** of housing **101** is characterized by a cut-out **106** formed therein for receiving a window insert **150** having a window **151** and a button **152**.

Pen body assembly **100** further includes a nut **110** having opposed proximal and distal ends **111** and **112**, respectively. Exterior surface regions of nut **110** between proximal and distal ends **111** and **112** define a plurality of longitudinally extending splines **113**. Proximal end **111** of nut **110** is characterized by a plurality of longitudinally extending resilient fingers **114** with enlarged ends that enable snap engagement of nut **110** into other portions of pen body assembly **100** as explained further herein. Distal end **112** of nut **110** is radially enlarged to limit axial movement of nut **110** into distal end **103** of housing **101**. Thus, nut **110** is axially constrained within housing **101**. However, the dimensions and configurations of nut **110** and housing **101** permit free relative rotation therebetween.

Pen body assembly **100** further includes a clutch assembly having a proximal clutch **141**, a distal clutch **143** and an annular spring **142** biasingly engaged therebetween. Proximal and distal clutches **141** and **143** are both configured for non-rotatable engagement over splines **113** of nut **110**. Distal clutch **143** includes an array of distally facing saw teeth (not shown) dimensioned, disposed and configured for engagement with the teeth (not shown) on interior surface **108** of housing **101**, such that distal clutch **143** can rotate only in one direction relative to housing **101**. Proximal clutch **141** includes an array of proximally facing teeth (not shown) which are also configured for unidirectional rotation as explained further herein.

Pen body assembly **100** further includes a drive mechanism having a generally cylindrical driver **50** with opposed proximal and distal ends **451** and **452**. Driver **450** is slidably inserted into housing **101** of pen body assembly **100** such that distal end **452** of driver **450** is snap fit over the enlarged ends of resilient fingers **114** at proximal end **111** of nut **110**. This snap fit engagement prevents axial movement between nut **110** and driver **450**, but permits free relative rotational movement within housing **101**. Distal end **452** of driver **450** is also characterized by an array of saw teeth (not shown) that engage with the saw teeth on proximal clutch **141**. Outer surface regions of driver **450** are characterized by splines **454** extending radially outwardly thereon and along a substantial portion of the length of driver **450**.

Pen body assembly **100** further includes a dose knob **400** which is a hollow generally cylindrical structure having opposed proximal and distal ends **401** and **402** and opposed inner and outer surfaces. As shown in FIG. **6**, the inner surface is characterized by longitudinally extending grooves **405** which are disposed and dimensioned for engagement with splines **454** on driver **450**. More particularly, dose knob **400** is spline mounted over driver **450** within housing **101** of pen body assembly **100**. Thus, axially extending grooves **405** in dose knob **400** engage splines **454** of driver **450** to prevent relative rotation therebetween, but permitting relative axial movement. The outer surface of dose knob **400** is characterized by a helical groove **403** with dosage indicia to define dose amounts corresponding to different positions along helical groove **403**. Proximal end **401** of dose knob **400** is characterized by a gnarled exterior surface to facilitate manipulation for setting a selected dose having an

actuator button **407** snapped therein to permit relative rotation therebetween.

Insert **150** is snapped into engagement with cut-out **106** in the proximal end **102** of housing **101**. Insert **150** includes a window **151** therethrough and button **152** on an interior face that is dimensioned and disposed to engage with helical groove **403** on dose setting knob **400**. Button **152** and window **151** are disposed to also enable the dosage indicia on dose setting knob **400** to be visible through window **151** as dose knob **400** is rotated.

Pen body assembly **100** includes a lead screw **120** with opposed proximal and distal ends **121** and **122** and an array of external threads **123**. External threads **123** are characterized, however, by a pair of opposed axially extending grooves **124** which extend from an enlarged head **125** at distal end **122** substantially to the proximal end **121**. Threads **123** are threadably engaged in nut **110**, such that proximal end **121** of lead screw **120** is within housing **101** and distal end **122** projects distally beyond housing **101**. Threads **123** on lead screw **120** have exactly the same pitch and the same hand as threads **105** on distal end **103** of housing **101**.

Pen body assembly **100** further includes an anti-rotation ring **160**, shown in FIGS. **2–5**, having a pair of tabs **161** extending therein and splines **162** on its distal surface. Each tab **161** slidable engages groove **124** on lead screw **120** to allow anti-rotation ring **160** to travel on and rotate with lead screw **120**. Thus, lead screw **120** can slidably move relative to anti-rotation tabs **161**, but is prevented from rotating relative to anti-rotation tabs **161**.

Pen body assembly **100** is assembled by placing nut **110** into housing **101** from distal end **103**. Clutch assembly **141,142** and **143** then is mounted over splines **113** on nut **110**. Driver **450** is then inserted into proximal end **102** of housing **101**, and is urged sufficiently in a distal direction for snap fit engagement with nut **110**. In this snapped engagement, the saw teeth of distal clutch **143** will be secured in engagement with the teeth in of housing **101**, and the saw teeth of proximal clutch **141** will be engaged with the saw teeth at distal end **452** of driver **450**. Spring **142** will maintain constant selected pressure between these interengaged saw teeth. Insert **156** then is positioned over dose knob **400** such that button **152** of insert **150** is engaged in the helical groove **403** in dose knob **400**. The temporarily assembled insert **150** and dose knob **400** then are into housing **101**. Lead screw **120** then is threaded into nut **110**, and actuator button **407** is snapped into engagement with proximal end **401** of dose knob **400**. Finally, anti-rotation ring **160** is slid onto lead screw **120** and a retaining ring **163** on ring **160** is rotatably attached to a receiving ring **165** at distal end **103** of pen housing **101**.

Cartridge holder assembly **300**, shown in detail in FIGS. **2** and **3**, includes a molded housing **304** which extends from proximal end **301** to distal end **302** of cartridge holder assembly **300**. Housing **304** includes a mounting cavity **305** extending inwardly from proximal end **301**. Mounting cavity **305** is characterized by an array of internal threads **303** for threaded engagement with external threads **105** on distal end **103** of housing **101**. A set of splines **306** are located in proximal end **301** of cartridge holder assembly **300** to receive splines **162** on anti-rotation ring **160** when cartridge holder assembly **300** is threaded onto housing **101** to prevent cartridge holder assembly **300** from rotating with respect to lead screw **120** but continue to rotate with respect to pen housing **101**. However, when pen **10** is fully assembled, splines **162** are fully engaged with splines **306** so that lead screw **120** is then engaged with the remaining drive mechanism in the pen and ready for dose setting and dispensing operations.

Cartridge holder assembly **300**, further includes a medication cartridge **350** securely retained in housing **304** between proximal end **301** and distal end **302**. Medication cartridge **350** includes an open proximal end **351** and a distal end **352** having a pierceable elastomeric seal **353** securely mounted thereto. A cap **354** extends between housing **304** and cartridge **350** for securely and permanently holding medication cartridge **350** in housing **304**. A plunger **355** is disposed in sliding fluid tight engagement in cartridge **350**. As shown in FIG. **3**, plunger **355** is disposed in primed contact with plunger **355** of medication cartridge **350** when fully threaded to cartridge holder assembly **300**. Portions of cartridge **350** between plunger **355** and seal **353** are filled with a medication **356**, such as insulin.

Needle cannula assembly **500** includes a double ended needle cannula **501** having opposed proximal and distal points **502** and **503**, respectively, and a lumen extending axially therebetween. A mounting hub **504** is engaged on needle cannula **501** and is threadably engageable with cap **354** of cartridge holder assembly **300**. The relative location of mounting hub **504** ensures that proximal point **502** of needle cannula **501** will pierce seal **353** when mounting hub **504** is engaged with cap **354**. Needle cannula assembly **500** further includes a shield **600** removably mounted thereon for protecting against accidental needle sticks until immediately prior to use of pen **10**.

As noted above, pen body assembly **100** is reusable and cartridge holder assembly **300** is disposable. More particularly, cartridge **350** in cartridge holder assembly **300** will contain a volume of medication **356** sufficient for administration of several doses. After exhaustion of the medication **356**, cartridge holder assembly **300** will be threadedly disengaged from pen body assembly **100** and discarded. A new cartridge holder assembly **300** may then be mounted to the reusable pen body assembly **100**.

To effect the mounting of a new cartridge holder assembly **300** to the reusable pen body assembly **100**, the patient need merely advance distal end **122** of lead screw **120** into cartridge holder assembly **300** until distal end **122** of lead screw **120** engages plunger **355**. Assembly continues by merely exerting axial forces on actuator button **407** and on cartridge holder assembly **300** Additionally, friction between plunger **355** and cartridge **350** and fluid forces exerted by medication **356** and seal **353** will prevent axial advancement of lead screw **120** beyond the position depicted in FIG. **3** during assembly. Additionally, the splined engagement of distal clutch **143** with nut **110** and the engagement of the teeth on distal clutch **143** with the corresponding teeth in housing **101** prevent independent rotation of nut **110** with respect to housing **101**, during this initial mounting of reusable pen body assembly **100** with a new cartridge holder assembly **300**. Therefore, axial forces exerted on actuator button **407** will cause housing **101** to rotate and advance towards cartridge holder assembly **300** as nut **110** rotates on threads **123** of lead screw **120**.

After sufficient axial advancement, threads **105** at distal end **103** of pen body housing **101** will engage internal threads **303** at proximal end **301** of cartridge holder assembly **300**. As noted above, external threads **105** at distal end **103** of housing **101** have exactly the same pitch and hand as threads **123** on lead screw **120**. Hence, further axial forces exerted on actuator button **407** will cause the simultaneous threaded advancement of housing **101** along lead screw **120** and into cavity **305** at proximal end **301** of cartridge holder assembly **300**. Because of the identical pitches, lead screw **120** will move proximally relative to pen body housing **101**, while pen body housing **101** and cartridge holder assembly

300 are approaching their fully seated and threaded condition. When fully seated and threaded, lead screw 120 is fully engaged to the drive mechanism and can be driven by the drive mechanism when medication dispensing is desired.

The assembled reusable pen body assembly 100 and cartridge holder assembly 300 may be stored until a selected dose of medication is required. Just prior to use, a needle cannula assembly 500 may be threadedly engaged to distal end 302 of cartridge holder assembly 300. This threaded engagement will cause proximal point 502 of needle cannula 501 to pierce seal 353 and provide communication with medication 356. Shield 600 may then be removed.

A desired dose of medication 356 is then set by rotating dose knob 400 until indicia corresponding to the desired dose appears in window 151 of insert 150. The engagement of button 152 on insert 150 in helical groove 403 in dose knob 400 will cause a threaded retraction of dose knob 400 relative to housing 101 of reusable pen body assembly 100. This threaded retraction of dose knob 400 will cause a simultaneous rotation of driver 450 splined thereto. However, nut 110 will not rotate because the saw teeth on distal clutch 143 and the saw teeth on interior portions of housing 101 are locked to prevent rotation in that direction. Proximal clutch 141 is splined to nut 110, and hence also will not turn. However, saw teeth 453, shown in FIG. 6, at distal end 452 of driver 450 are shaped to allow rotation relative to proximal clutch 141 and provide an audible click for each unit of medication in the selected dose. This is helpful for visually impaired patients who may be required to set doses and administer insulin or other medication to themselves. Annular spring 142 contributes to the engagement that provides these audible clicking sounds.

When the desired dose is set, injection is achieved by merely pushing on actuator button 407. This causes dose knob 400 to turn about helix 403 relative to pen body housing 101, and driver 450 rotates through the same number of degrees. This rotation is opposite to the rotation generated by the dose setting procedure, and the rotational freedom of the clutch assembly 140 is reversed. Thus, as driver 450 turns the previously clicking proximal clutch 141 is locked to and turns with driver 450. This driving movement of proximal clutch 141 causes a corresponding rotational movement of nut 110 because of the splined engagement therebetween. Distal clutch 143 is now free to rotate against the saw teeth on housing 101, and makes an audible clicking indication during injection of medication.

Rotation of lead screw 120 is prevented by splines 306 unitary molded in cartridge holder assembly 300 mating with splines 162 on anti-rotation ring 160 engaged with lead screw 120 and causes lead screw 120 to be engaged with the drive mechanism. Therefore, as nut 110 rotates under the driving action of proximal clutch 141 and driver 450, lead screw 120 will be advanced axially into cartridge holder assembly 300. This axial advancement of lead screw 120 causes distal end 122 to urge plunger 355 distally into cartridge 350, and hence causes medication 356 to be injected through needle cannula 501. Injection will be terminated when proximal end 401 of dose knob 400 engages proximal end 102 of pen body housing 101.

Upon completion of the injection, needle cannula assembly 500 may be disengaged from cartridge holder assembly 300 and safely discarded. Cap 200 may be mounted over cartridge holder assembly 300, and pen 10 may be stored or carried in a convenient location until the next dose of medication is required. A subsequent dose of medication will be set in exactly the manner as described above. However, for such a subsequent dose, lead screw 120 and plunger 355 will be in a partly advanced position as a starting point. Dose setting and injections can be carried out until all of medication 356 has been used. Cartridge holder assembly 300 may then be threadedly disengaged from pen body assembly 100, and slidably separated from lead screw 120. The separated cartridge holder assembly may then be discarded and replaced as described above.

While the invention has been described with respect to a preferred embodiment, it is apparent that various changes can be made without departing from the scope of the invention as defined by the appended claims. In particular, the reusable pen body assembly may have other driving and/or clutch mechanisms. Additionally, different means for preventing and/or enabling rotation during the dose setting and injection phases may be provided. Similarly, other means for mounting needle cannula to the cartridge holder assembly may be provided. These various optional constructions will be apparent to those skilled in the an after having read the subject disclosure.

What is claimed is:

1. A medication delivery pen comprising:

a cartridge holder assembly for holding a cartridge having a plunger, said cartridge holder assembly having a plurality of threads at a proximal end; and

a pen body assembly releasably mountable on said cartridge holder assembly of said medication delivery pen for moving said plunger within said cartridge, said pen body assembly comprising:

a plurality of threads at a distal end for threading with said plurality of threads in said cartridge holder assembly;

a lead screw extending from the distal end for engaging the plunger in the cartridge in said cartridge holder;

means in said pen body assembly for driving said lead screw into said cartridge to move the plunger in the distal direction;

means in said pen body assembly for disengaging said driving means from said lead screw to permit said lead screw to automatically and easily retract into said pen body assembly as said pen body assembly approaches and is being threaded to said cartridge holder assembly; and

means in said pen body assembly for engaging said driving means to said lead screw to prime said medication delivery pen, when said pen body assembly is fully threaded onto said cartridge holder assembly,

wherein said means for disengagin and means for engaging include:

an anti-rotation ring slidably mounted on said lead screw to prevent said lead screw from rotating with respect thereto, said anti-rotation ring having a spline extending in the distal direction into said cartridge holder assembly; and

a spline located within said cartridge holder assembly for mating with said spline on said anti-rotation ring to prevent said lead screw from rotating with respect to said cartridge holder assembly and engage said lead screw to said driving means, when said pen body assembly is fully threaded onto said cartridge holder assembly.

2. A medication delivery pen according to claim 1, wherein said lead screw includes a longitudinal groove and said anti-rotation ring includes a tab that is received in said groove to prevent said lead screw from rotating with respect to said anti-rotation ring.

3. The medication delivery pen of claim 1, wherein said cartridge holder assembly further comprises a housing unitarily molded from a plastic material with said spline being a unitary portion of said housing.

4. A medication delivery pen according to claim 1, wherein:

said plurality of threads in said pen body assembly are dimensioned and have a pitch for threaded engagement with said plurality of threads at the proximal end of said cartridge holder assembly; and

said lead screw further comprises a proximal end disposed in said pen body assembly with an array of threads extending between the proximal end and the distal end of said lead screw and having a pitch substantially equal to said pitch of said plurality of threads in said pen body assembly.

5. The medication delivery pen of claim 1, wherein said pen body assembly further comprises dose setting means in said pen body assembly for defining specified distances of travel for said lead screw corresponding to selected doses of medication to be delivered.

6. The medication delivery pen of claim 1, further comprising a needle cannula assembly that is selectively engageable and disengageable from the distal end of said cartridge holder assembly.

7. A medication delivery pen comprising:

a cartridge holder assembly for holding a cartridge having a plunger, said cartridge holder assembly having a plurality of threads at a proximal end; and

a pen body assembly releasably mountable on said cartridge holder assembly of said medication delivery pen for moving said plunger within said cartridge, said pen body assembly comprising:

a plurality of threads at a distal end for threading with said plurality of threads in said cartridge holder assembly;

a lead screw extending from the distal end for engaging the plunger in the cartridge in said cartridge holder;

means in said pen body assembly for driving said lead screw into said cartridge to move the plunger in the distal direction;

means in said pen body assembly for disengaging said driving means from said lead screw to permit said lead screw to automatically and easily retract into said pen body assembly as said pen body assembly approaches and is being threaded to said cartridge holder assembly; and

means in said pen body assembly for engaging said driving means to said lead screw to prime said medication delivery pen, when said pen body assembly is fully threaded onto said cartridge holder assembly,

wherein said means for disengaging and means for engaging include:

an anti-rotation ring slidably mounted on said lead screw to prevent said lead screw from rotating with respect thereto, said anti-rotation ring having a plurality of splines extending in the distal direction into said cartridge holder assembly; and

a plurality of splines located within said cartridge holder assembly for mating with said plurality of splines on said anti-rotation ring to prevent said lead screw from rotating with respect to said cartridge holder assembly and engage said lead screw to said driving means, when said pen body assembly is fully threaded onto said cartridge holder assembly.

8. A medication delivery pen comprising:

a medication-containing cartridge holder assembly including:

an open proximal end having an array of threads,

a cartridge having a pierceably sealed distal end, and

a plunger in sliding fluid tight engagement within said cartridge at a location distally of said array of threads; and

a pen body assembly releasably mountable on said medication-containing cartridge holder assembly of said medication delivery pen for moving said plunger within said cartridge, said pen body assembly having:

a housing surrounding said pen body assembly and having opposed proximal and distal ends, said distal end having an array of threads dimensioned and having a pitch for threaded engagement with said array of threads at said proximal end of said medication-containing cartridge holder assembly,

a lead screw having a proximal end disposed in said housing, a distal end projecting beyond said distal end of said housing for selective engagement with said plunger, and an array of threads extending between said proximal and distal ends of said lead screw and having a pitch substantially equal to said pitch of said array of threads at said distal end of said pen body assembly,

driver means in said pen body assembly for moving said lead screw distally into said pen body assembly by preselected amounts,

dose setting means in said pen body assembly for defining specified distances of distal travel for said lead screw corresponding to selected doses of medication to be delivered and causing said driver means to move said lead screw distally a preselected amount corresponding to a selected dose, and

means in said pen body assembly for engaging said lead screw and said driver means and preventing said lead screw from moving in a proximal direction into said pen body assembly, when said pen body assembly is fully threaded onto said medication-containing cartridge holder assembly.

9. A medication delivery pen according to claim 8, wherein said means for engaging said lead screw and said driver means and preventing said lead screw from moving in a proximal direction into said pen body assembly include:

an anti-rotation ring slidably mounted on said lead screw to prevent said lead screw from rotating with respect thereto, said anti-rotation ring having a spline extending in the distal direction into said medication-containing cartridge holder assembly; and

a spline located within said medication-containing cartridge holder assembly for mating with said spline on said anti-rotation ring to prevent said lead screw from rotating with respect to said medication-containing cartridge holder assembly and engage said lead screw to said driver means, when said pen body assembly is fully threaded onto said medication-containing cartridge holder assembly.

* * * * *

EXHIBIT 7

United States Patent [19] [11] **Patent Number: 4,973,318**

Holm et al. [45] **Date of Patent: Nov. 27, 1990**

[54] **DISPOSABLE SYRINGE**

[75] Inventors: **Niels E. Holm**, Birkerod; **Allan Spork**, Lyngby; **Klaus Thogersen**, Klampenborg; **Anders Bressendorff**, Virum; **Jorn Rex**, Roskilde, all of Denmark

[73] Assignee: **D.C.P. AF 1988 A/S**, Denmark

[21] Appl. No.: **308,399**

[22] Filed: **Feb. 9, 1989**

[30] **Foreign Application Priority Data**

Feb. 10, 1988 [DK] Denmark 692/88

[51] **Int. Cl.**[5] **A61M 5/00**

[52] **U.S. Cl.** **604/208**; 604/211; 604/218

[58] **Field of Search** 604/206, 207, 208, 209, 604/210, 211, 187, 232, 236, 246, 248, 192, 263, 71, 72, 186, 218

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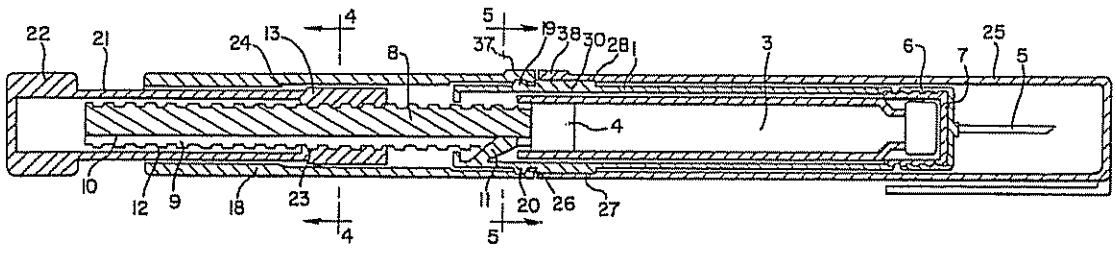
Primary Examiner—John D. Yasko
Attorney, Agent, or Firm—Willian Brinks Olds Hofer Gilson & Lione

[57] **ABSTRACT**

A disposable syringe includes first and second housing elements which are coupled together for rotation without axial movement therebetween. The first housing element receives a cartridge of a solution to be injected, and mounts a liquid outlet needle at its front end. A piston rod is disposed in the second housing element to move axially therein, and this piston rod includes a rod element and a nut element. The rod element is coupled to the first housing element to move axially therein without relative rotation therewith, and the nut element is threaded to the rod element for telescoping movement therewith and is configured to move axially in the second housing element without relative rotation therein. A pressure receiving element is mounted on the nut element. The housing, rod, nut and pressure receiving elements cooperate such that relative rotation between the housing elements in a selected direction causes relative rotation between the nut and rod elements and thereby increases the effective length of the piston rod and causes the pressure receiving element to extend from the second housing element. A protective cap is removably mounted over the first housing element and is configured to abut second housing element while mounted in place on the first housing element. This protective cap is engaged with the first housing element such that rotation of the cap with respect to the second housing element causes rotation of the first housing element with respect to the second housing element.

30 Claims, 9 Drawing Sheets



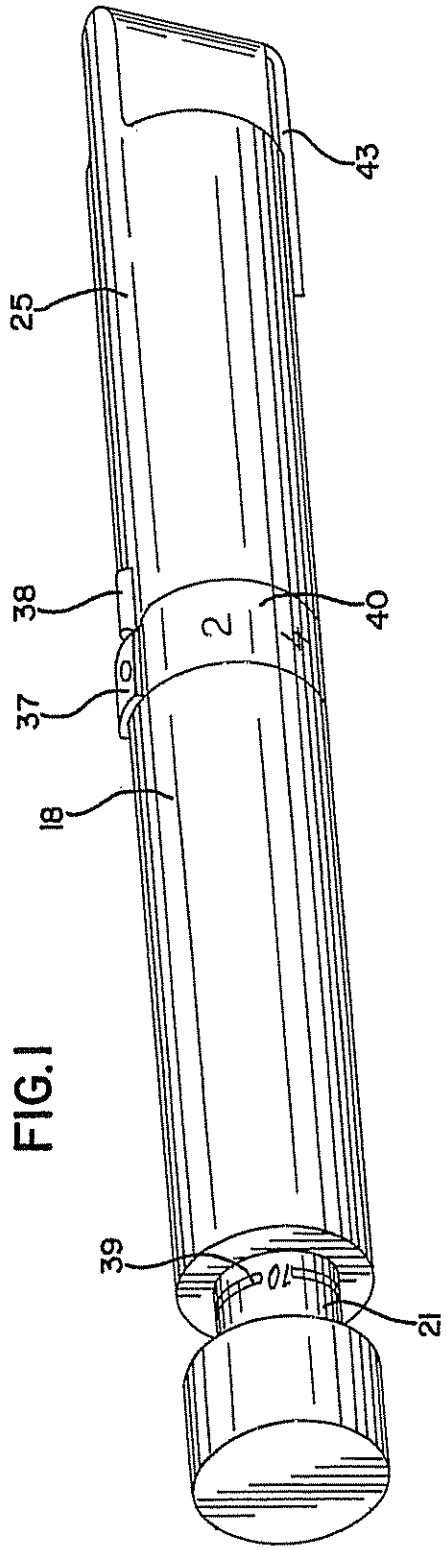


FIG. 1

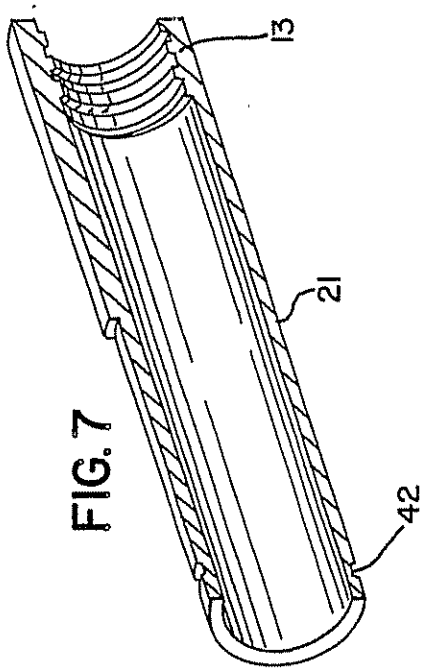


FIG. 7

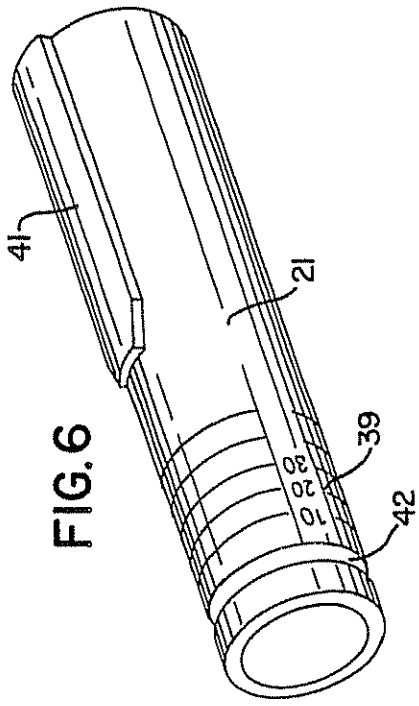


FIG. 6

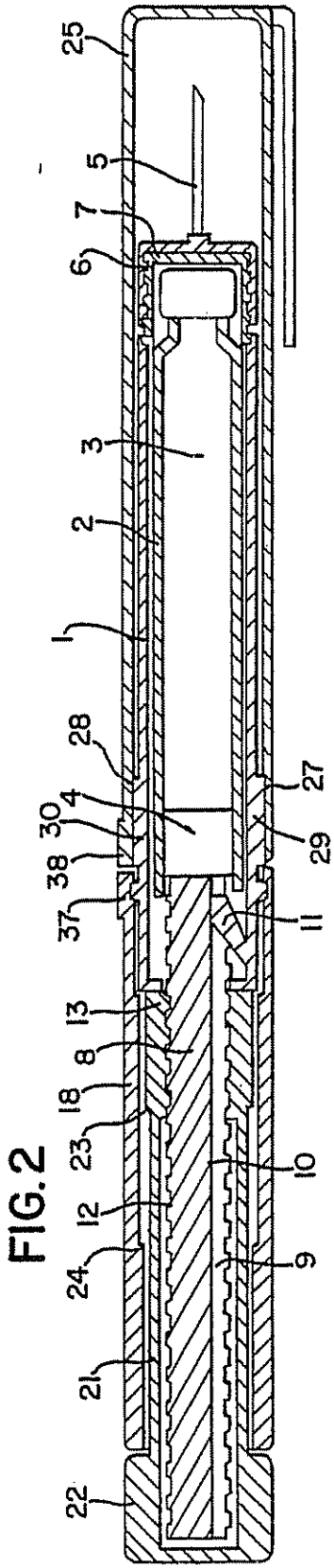


FIG.2

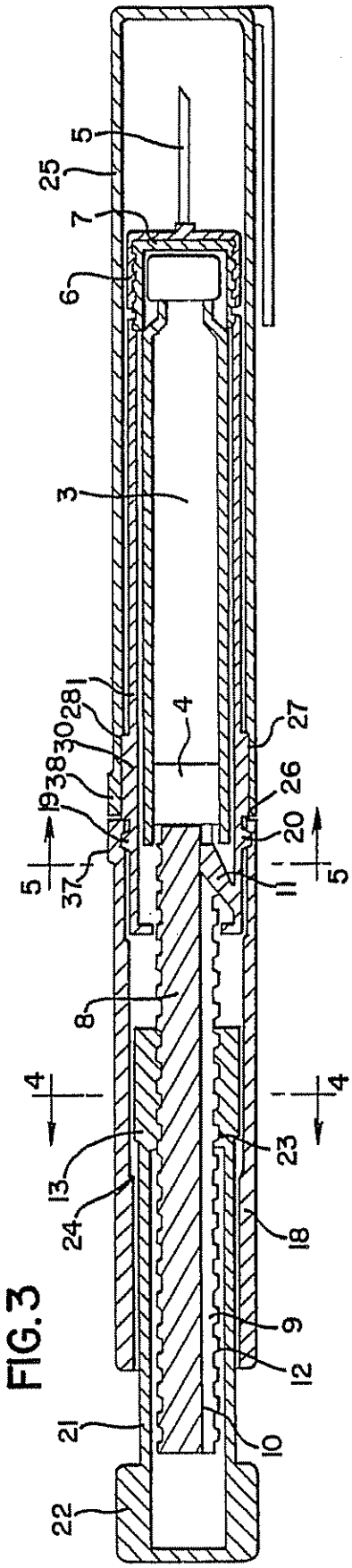


FIG.3

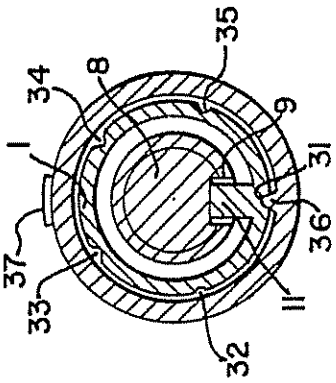


FIG.5

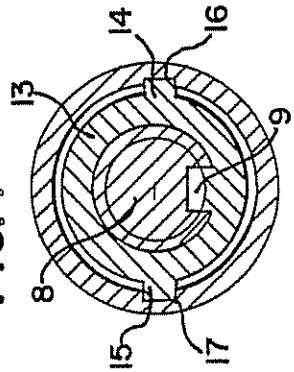


FIG.4

FIG. 8

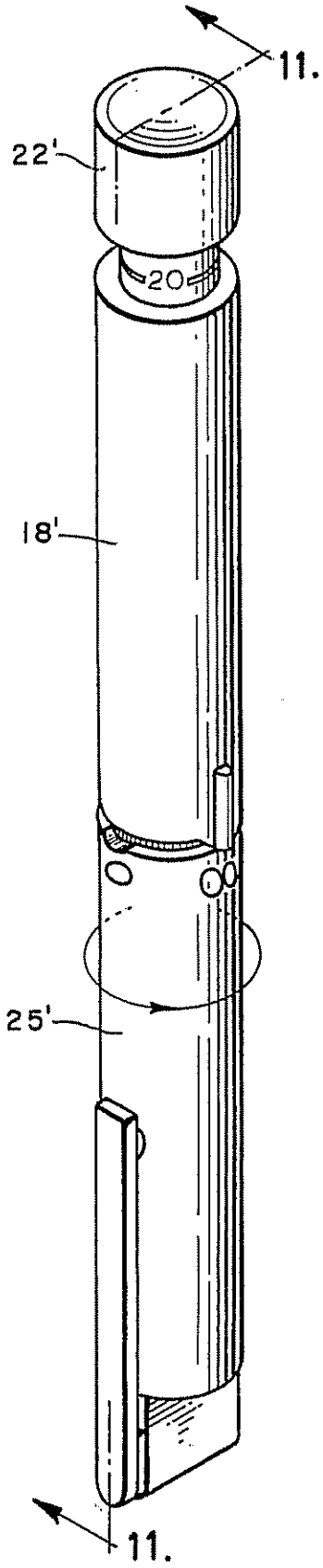


FIG. 9

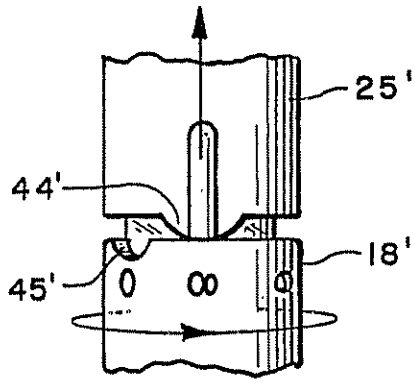


FIG. 10

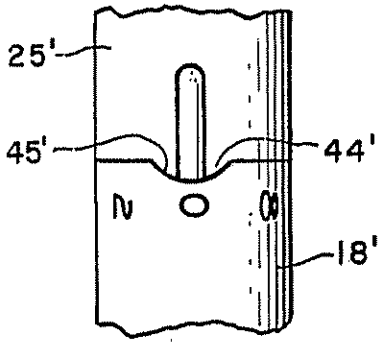


FIG. 12

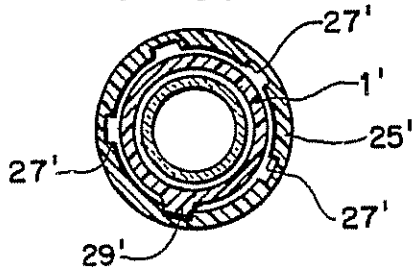


FIG. 13

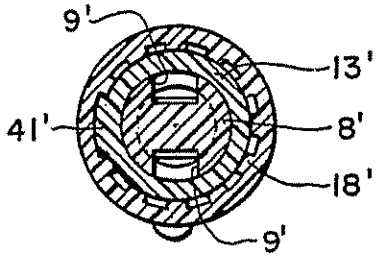


FIG. 11

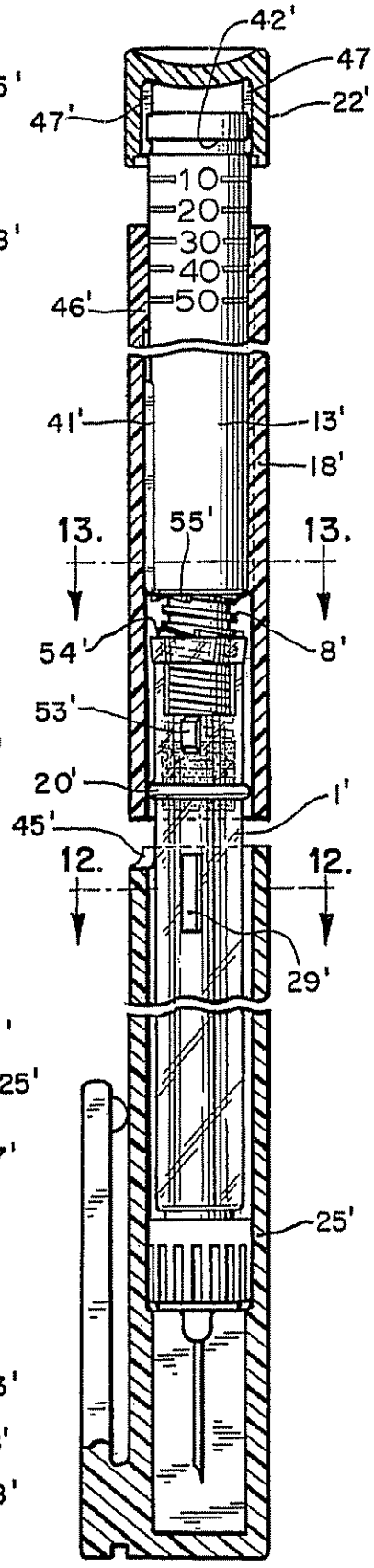


FIG. 14

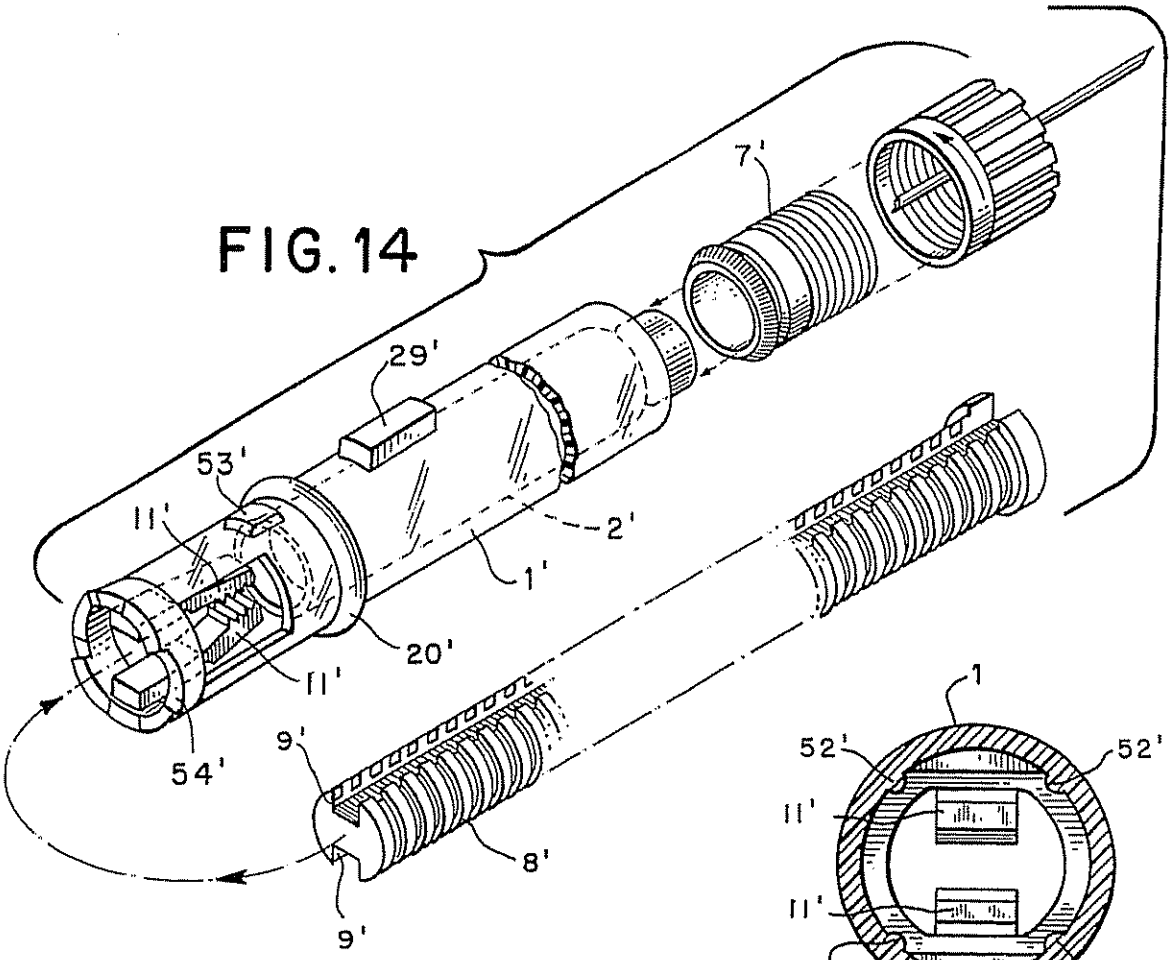


FIG. 16

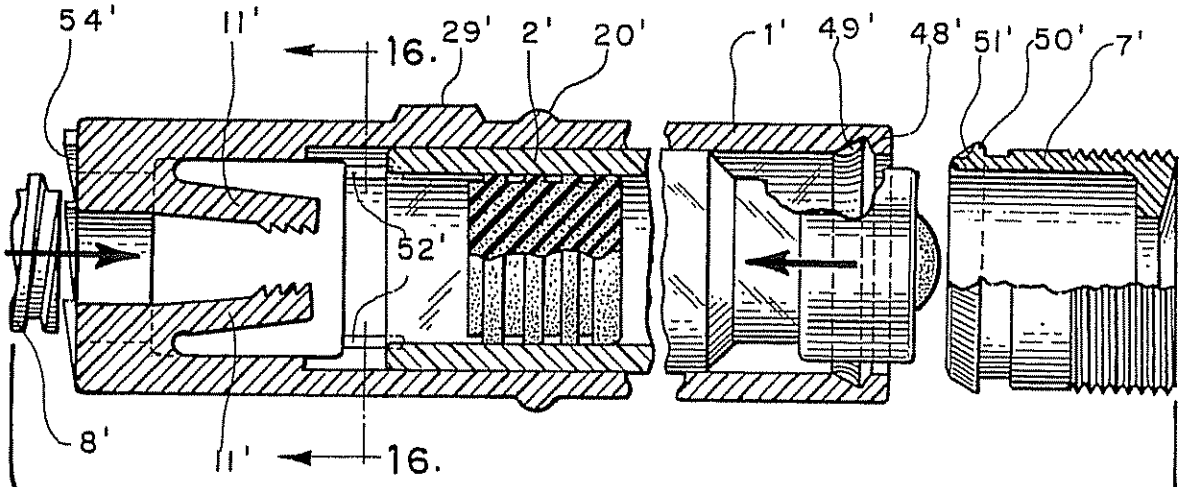


FIG. 15

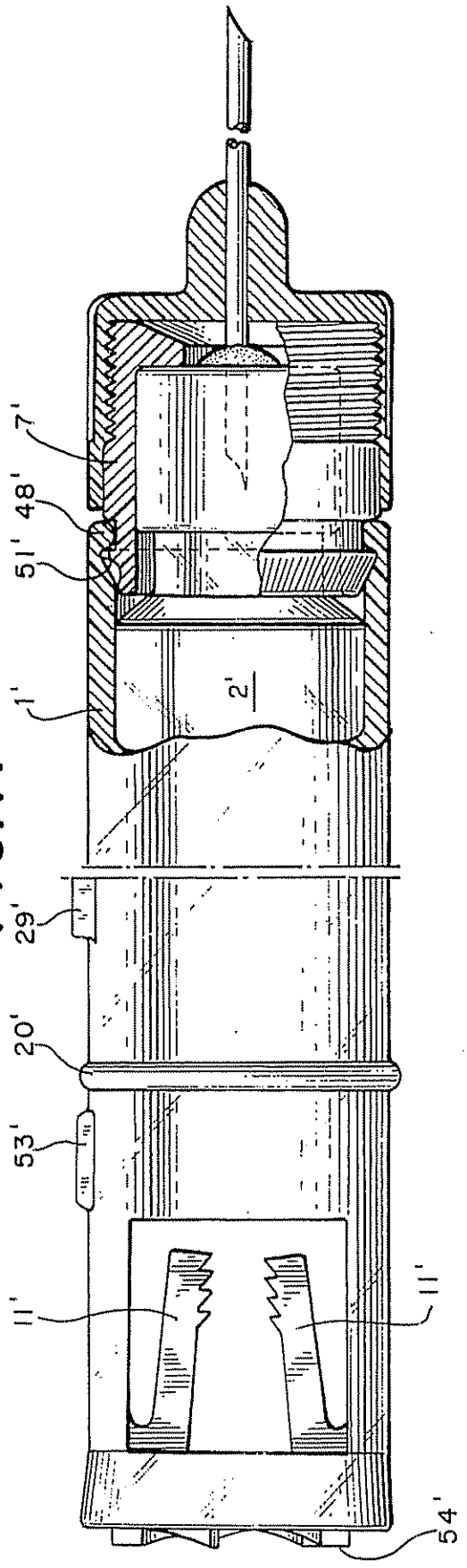


FIG. 17

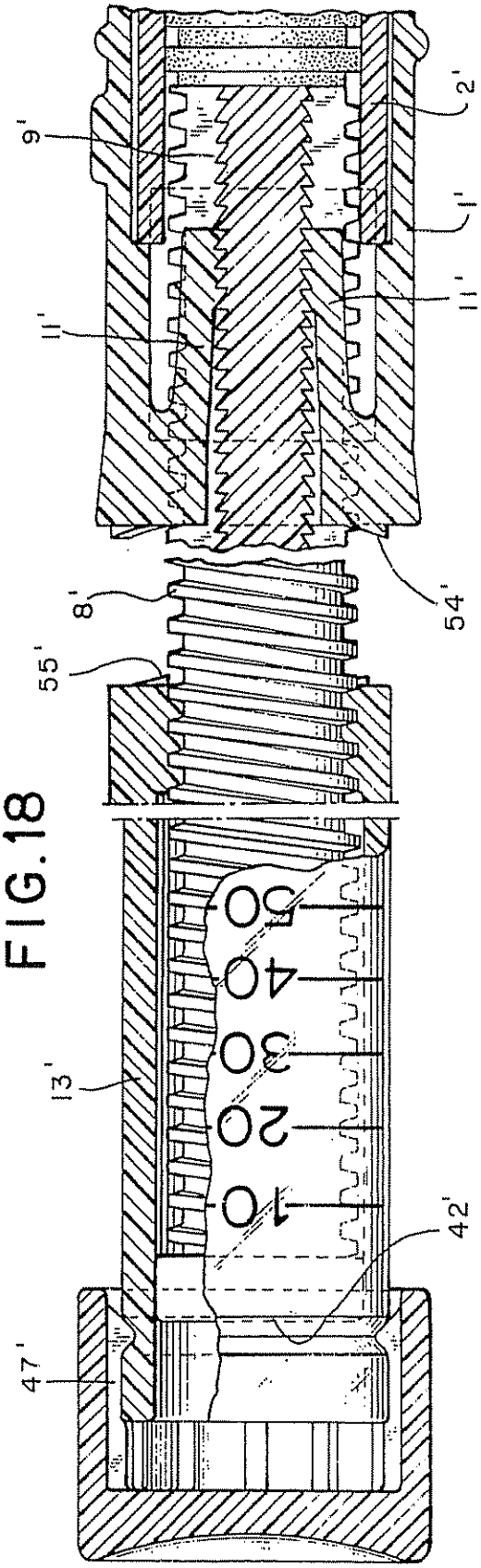


FIG. 18

FIG. 19

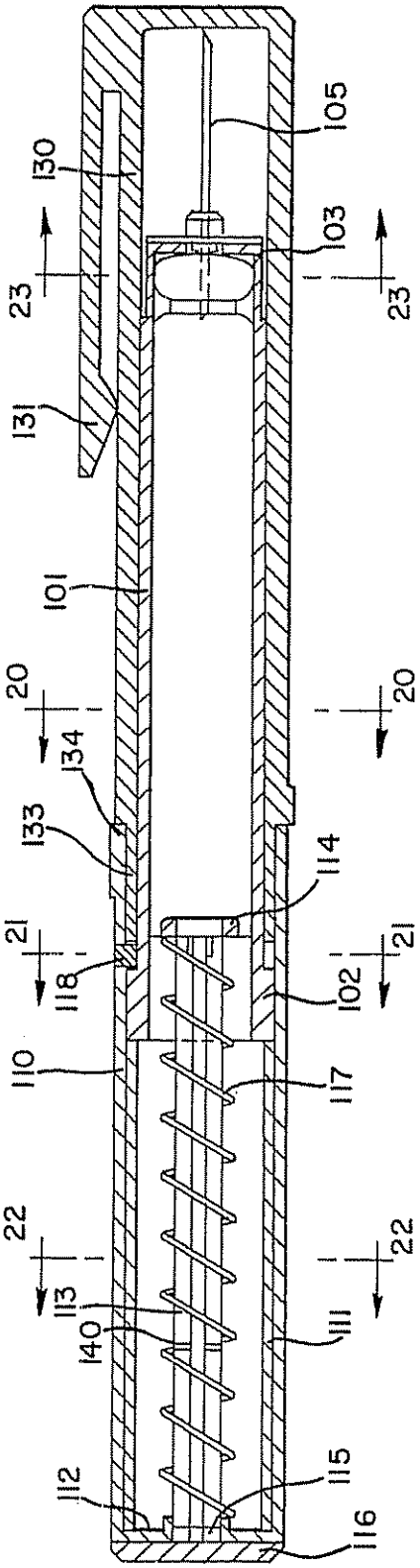

105
130
103
23
23
131
101
20
20
134
133
114
21
21
118
102
110
117
22
22
113
111
140
115
112
116

FIG. 20

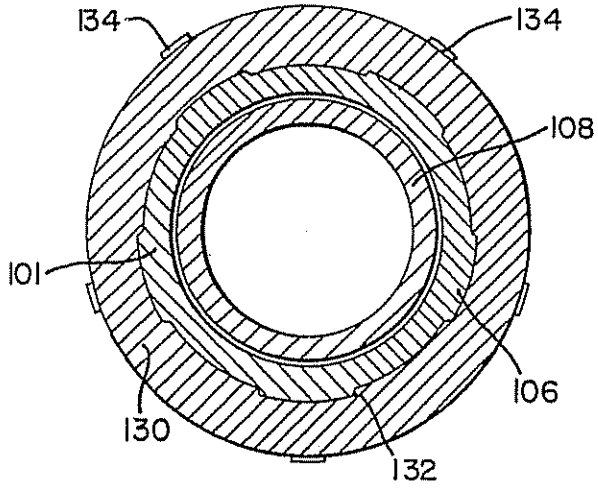


FIG. 21

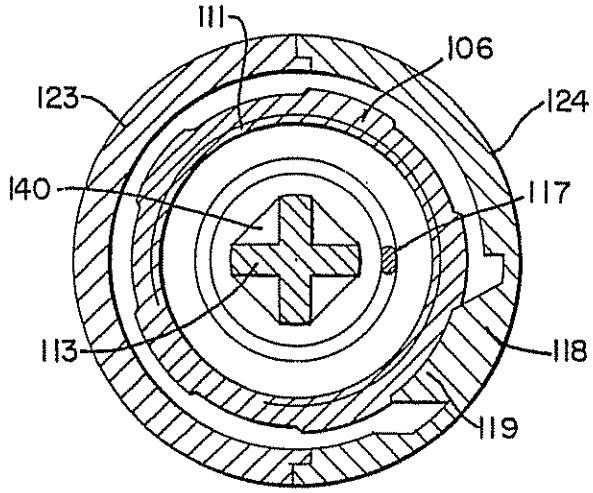


FIG. 22

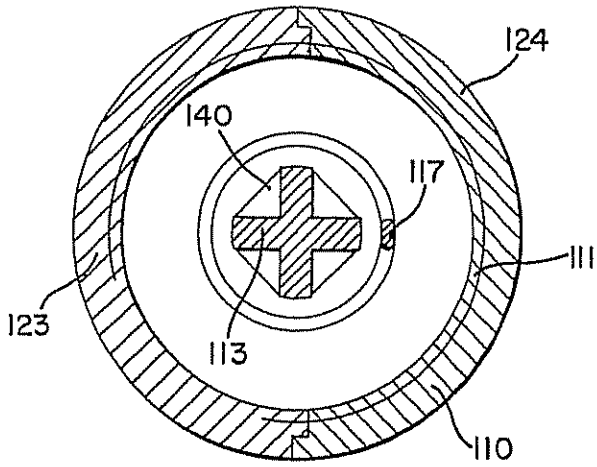
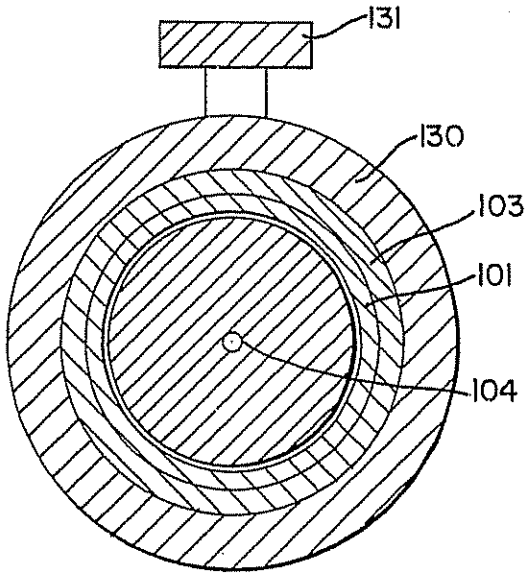


FIG. 23



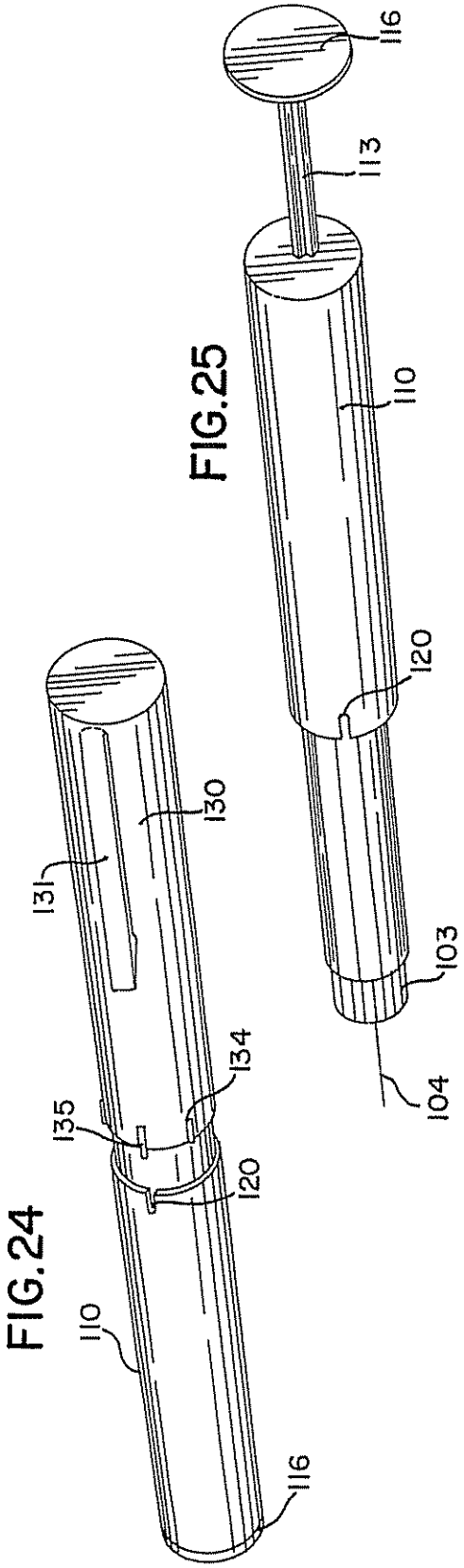


FIG.25

FIG.24

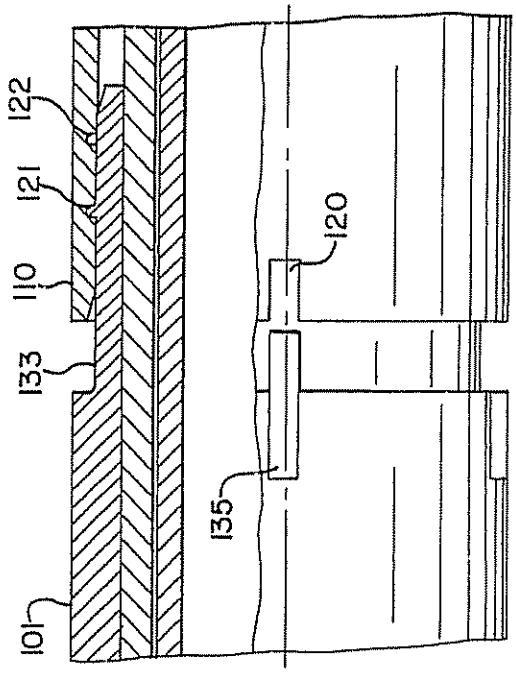


FIG.27

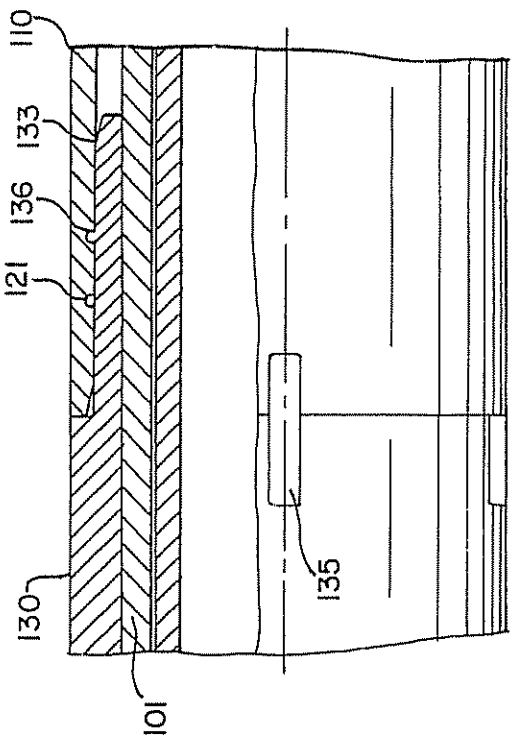


FIG.26

DISPOSABLE SYRINGE

TECHNICAL FIELD

This invention relates to a disposable syringe for injecting preset doses of a liquid contained in the syringe. The syringe of this invention is particularly but not exclusively applicable for delivering preset dosages of insulin, and the following description relates to a device for the injection of insulin solutions. However, it is to be understood that the syringe of this invention is also suitable for the injection of preset dosages of other liquids.

In particular, this invention relates to a syringe or dosage unit of the type that comprises first and second housing elements coupled together to allow rotation of the first housing element with respect to the second housing element, wherein the first housing element is adapted to receive a quantity of liquid and comprises means for mounting a liquid outlet needle in the front end thereof, and wherein the second housing element has a rear end situated opposite the front end of the first housing element.

BACKGROUND ART

Diabetics have to inject themselves repeatedly with insulin solution, and the volume of insulin solution to be injected may vary from injection to injection. For this reason, diabetics need syringes which allow them to inject successive measured dosages of the same or different preset volumes of insulin solution.

A wide variety of syringes have been proposed. For example, International Patent publication No. WO 82/02662 discloses a dose metering device for use with a syringe. The metering device utilizes a manually rotatable cap which axially moves the piston in the syringe. The volume delivered by the syringe is determined by the angular stroke of the cap. This device is not fully satisfactory for use by diabetics, because it requires two hands to hold the syringe and rotate the cap. For this reason, a diabetic cannot use this device to inject insulin into a skin fold, as recommended by many physicians.

Another drawback of the above-mentioned dose metering device is that production costs are so high that in practice it must be re-used. This necessitates replacement of the syringe or at least a cartridge with a new one. During the reloading operation, dust or other contaminants may be introduced into the metering device and this may adversely affect the operation of the metering device. Furthermore, there are more and more different commercially available insulin preparations, and therefore there is an increasing risk that a patient may insert a syringe or cartridge containing an insulin preparation other than the required one. Furthermore, reloading requires a series of operations which although not complicated may yet be troublesome for the patient.

It is therefore an object of this invention to provide a syringe that is so simple and inexpensive that it can be discarded after use.

Another object of this invention is to provide a syringe capable of delivering a number of accurate preset doses without reloading.

A further object of the invention is to provide a syringe which can be used for a single handed operation, with preadjustment of the total quantity to be injected.

A further object of the invention is to provide a syringe of such dimensions that it can be carried in a pocket like a writing pen.

Yet another object of this invention is to provide a dosage unit that maintains a constant length in use.

SUMMARY OF THE INVENTION

According to a first aspect of this invention, a disposable syringe of the type described above comprises a piston rod disposed in the second housing element to move axially therein. This piston rod comprises a rod element and a nut element. The rod element is coupled to the first housing element to move axially therein without relative rotation therebetween; and the nut element is threaded to the rod element for telescoping movement therewith and is configured to move axially in the second housing element without relative rotation therebetween. A pressure receiving element is mounted on the nut element, and the housing, rod, nut and pressure receiving elements all cooperate such that relative rotation between the housing elements in a selected direction causes relative rotation between the rod and nut elements and thereby increases the effective length of the piston rod and causes the pressure receiving element to extend from the second housing element. In this way, a measured quantity of the liquid is expressed from the needle when the pressure receiving element is moved back toward the second housing element.

Preferably, the nut element defines an axial scale along its length and is used in combination with the second housing element to gauge the dosage of liquid to be administered. As described below, the first and second housing elements may be arranged to rotate with respect to one another without axial movement therebetween such that the first and second housing elements maintain a substantially constant overall length as liquid is progressively dispensed through the needle.

The disposable syringe described below is easily preadjusted to the desired dose and quantity by rotating the two housing elements with respect to one another. This causes the nut element to move along the rod element and the pressure receiving element to be axially displaced. The indicator or scale connected to the nut element thereby moves with respect to the second housing element, and the scale can be used to measure the quantity of liquid that will be dispensed when the pressure receiving element is pushed back toward the second housing element. When the pressure receiving element is pushed back to its initial position, the nut element engages the rod element and the rod element is prevented from rotating relative to the first housing element. For this reason, axial movement of the nut element results in movement of the rod element. Preferably, a ratchet device is installed between the first housing element and the rod element to insure that the rod element cannot be retracted once it is pushed into the first housing element.

The following detailed description describes a number of other advantageous features of the invention. For example, the nut element preferably comprises at least one radially protruding, axially extending projection on the outside of the nut element which slides in an associated axially extending groove of the inner surface of the second housing element. Preferably, the nut element is shaped to limit axial movement of the nut element out of the second housing element beyond the predetermined limit, and in this way to prevent the dosage unit from being adjusted to deliver a potentially dangerously high

dose of liquid. In the preferred embodiment described below, the nut element and the indicator on the nut element are integrally formed together, thereby minimizing the total number of parts and the cost of the system. In this embodiment the nut element is substantially axially symmetrically shaped, and the pressure receiving element at the external end of the nut element has an outer diameter that corresponds to the outer diameter of the second housing element. As a result, the axial movement of the nut element towards the distal or rear end of the second housing element is stopped in a simple manner.

This embodiment utilizes a rod element that is prevented from rotating relative to the first housing element by means of a ratchet device. As discussed below, at least one and preferably two pawls are provided on the first housing element, and these pawls engage longitudinal grooves in the rod element, which are provided with a suitable toothed configuration to cooperate with the pawls.

According to a second feature of this invention, a disposable syringe or dosage unit, which may, for example, be of the type described above, includes a protective cap that is removably mounted over the front end of the first housing element to protect the needle. Means are provided for releasably coupling the protective cap and the first housing element for rotation together such that rotation of the protective cap with respect to the second housing element causes rotation of the first housing element with respect to the second housing element.

Preferably, the protective cap is configured to receive the first housing element such that a front portion of the second housing element substantially abuts a rear portion of the protective cap when the protective cap is mounted in place on the first housing element. In the preferred embodiment described below, the abutting ends of the cap and the second housing element together comprise a scale for measuring relative rotation of the protective cap with respect to the second housing element. This scale allows the rotational position of the cap with respect to the second housing element, and therefore the dose to be injected, to be gauged precisely. The scale formed at the abutting ends of the cap and the second housing element indicates the rotational position of the cap in fractions of a full rotation, while the measuring scale associated with the nut element described above indicates the number of full rotations of the cap with respect to the second housing element.

In the preferred embodiment described below, the cap may be releasably engaged with the first housing element at any one of a number discrete rotational positions, and a plurality of detents are provided at corresponding increments of rotation of the first housing element with respect to the second housing element. With this arrangement it is always possible to situate the measuring scale portion of the cap opposite a fixed zero on the second housing element such that this zero position forms the basis for measuring rotation of the cap with respect to the second housing element. This is possible regardless of the detent position of the first housing element with respect to the second element, and it provides the important advantage that the user of the syringe is provided with a clear zero position at the start of each adjustment. This feature instills confidence in the user that the desired dosage has in fact been selected.

The invention itself, together with further objects and attendant advantages, will best be understood by reference to the following detailed description, taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a perspective view of a first preferred embodiment of a dosage unit according to the invention, said dosage unit being ready for injection of a predetermined quantity of liquid.

FIG. **2** is an axial sectional view of the dosage unit of FIG. **1** before the adjustment of a predetermined dosing quantity.

FIG. **3** is an axial sectional view through the dosage unit of FIG. **1**.

FIG. **4** is a sectional view taken along line **4—4** of FIG. **3**.

FIG. **5** is a sectional view taken along line **5—5** of FIG. **3**.

FIG. **6** is a perspective view of an embodiment of an indicator integrally formed with an associated nut member, with portions removed for the sake of clarity.

FIG. **7** is an axial sectional view of the nut member of FIG. **6**.

FIG. **8** is a perspective view of a second preferred embodiment of a dosage unit or disposable syringe according to this invention.

FIG. **9** is a partial view of the syringe FIG. **8**, showing the cap positioned to allow rotation of the cap with respect to the second housing element of the syringe.

FIG. **10** is a view corresponding to FIG. **9** showing the cap seated in its zero position against the second housing element.

FIG. **11** is a longitudinal sectional view taken along line **11—11** of FIG. **8**.

FIG. **12** is a cross-sectional view taken along line **12—12** of FIG. **11**.

FIG. **13** is a cross-sectional view taken along line **13—13** of FIG. **11**.

FIG. **14** is an exploded perspective view of components of the syringe of FIG. **8**.

FIG. **15** is an exploded breakaway longitudinal sectional view of selected components of FIG. **14**.

FIG. **16** is a cross-sectional view taken along line **16—16** of FIG. **15**.

FIG. **17** is a side view in partial cut-away of selected components of FIG. **14** in the assembled position.

FIG. **18** is a longitudinal sectional view of components of the syringe of FIG. **8**.

FIG. **19** is a longitudinal sectional view of a third embodiment of a dosage unit according to this invention.

FIG. **20** is a cross-sectional view taken along the line **20—20** of FIG. **19**.

FIG. **21** is a cross-sectional view taken along the line **21—21** of FIG. **19**.

FIG. **22** is a cross-sectional view taken along the line **22—22** of FIG. **19**.

FIG. **23** is a cross-sectional view taken along the line **23—23** of FIG. **19**.

FIG. **24** is a perspective view of the syringe of FIG. **19**, showing the cap partially removed.

FIG. **25** is a perspective view of the syringe of FIG. **19**, showing the cap fully removed.

FIG. **26** is a partial longitudinal sectional view of the syringe of FIG. **19**, showing the cap fully inserted into the second housing element.

FIG. 27 is a view corresponding to FIG. 26 showing the cap partially removed from the second housing element.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIGS. 1–7, 8–18 and 19–27 relate to first, second, and third embodiments of this invention, respectively. The first and second embodiments embody both aspects of the invention described above, while the third embodiment embodies only the second aspect of the invention.

Turning to FIGS. 1–7, the first embodiment comprises a first housing element or casing 1 for a cartridge 2 containing a liquid 3. The cartridge 2 comprises a piston 4 pressing the liquid 3 out through a needle 5 inserted in the opposite end, said needle being secured to the casing 1 in a generally known manner by screwing on of a cup-shaped cap 6. As indicated in FIGS. 2 and 3, the cartridge 2 can be retained in the casing by means of a retaining cap 7 optionally secured to the casing by a snapping effect. The retaining cap 7 allows introduction of a protruding end of the needle 5, said end optionally extending into the interior of the cartridge. This introduction and insertion of the needle 5 is preferably carried out during the screwing on of the needle-carrying cap 6 onto the retaining cap 7 of the casing 1.

At the end opposite the needle 5 the dosage unit comprises a piston rod member 8 driving the piston 4 in the cartridge 2. This piston rod member 8 comprises a longitudinal groove 9 provided in the bottom with transverse barbs 10, and the groove 9 is serrated when seen in a longitudinal section (FIG. 3). These barbs cooperate with a pawl 11 formed on the casing 1. The pawl 11 is provided with barbs which cooperate with the barbs 10 on the piston rod member 8. These barbs 10 and the pawl 11 are shaped so as only to allow displacement of the piston rod member 8 towards the piston 4 of the cartridge and to prevent displacement in the opposite direction. As indicated in FIG. 5, the pawl 11 and the groove 9 are of such a width that their cooperation prevents the piston rod member 8 from rotating relative to the casing 1.

The piston rod member 8 further comprises a thread 12 shaped along its external periphery, and a nut member 13 is screwed onto the thread 12. On the outside the nut member 13 comprises radially protruding projections 14 and 15 extending axially along the outer side of the nut member 13 and received in corresponding respective grooves 16 and 17 (FIG. 4) in a surrounding sleeve-shaped adjustment means or second housing element 18. At the end adjacent the casing 1 this adjustment means 18 comprises a circumferential groove 19 receiving a circumferential projection 20 on the casing 1. As a result the adjustment means 18 is rotatable with respect to the casing 1, yet it is prevented from moving axially.

The nut member 13 is integrally shaped with a tubular indicator 21 extending coaxially with the piston rod member 8 away from the casing 1 between the piston rod member 8 and the adjustment means 18. At the free end projecting outside the adjustment means 18, the indicator 21 comprises an end button or pressure receiving element 22 of substantially the same outer diameter as the adjustment means 18. As indicated in FIGS. 2 and 3, the nut member comprises a circumferential abutment surface 23 at the transition to the tubular indicator. Correspondingly, the adjustment means 18 comprises an inner circumferential abutment surface 24, the abutment surface 23 on the nut member abutting the abutment surface 24 to provide a predetermined stop position as the nut member is displaced in the axial direction relative to the adjustment means 18. The grooves 16 and 17 shaped on the inner side of the adjustment means 18 are of such an extent that the nut member 13 can move freely in the axial direction relative to the adjustment means between the adjacent end of the casing 1 and the inner abutment surface 24 on the adjustment means 18.

The dosage unit also includes a removable cap 25 protecting the needle 5 when the dosage unit is not used. This cap is of such an axial extent that when mounted, its free rim 26 is situated adjacent the adjustment means 18. Axial recesses or grooves are provided close to the free rim 26 of the cap 25, said recesses being situated symmetrically with the same mutual angular separation from one another along the inner side of the cap. These recesses are indicated by the reference numerals 27 and 28 in FIGS. 2 and 3 and receive correspondingly shaped protruding projections 29 and 30, respectively, on the outer side of the casing 1. In this manner the cap can always be situated in a predetermined rotational position relative to the periphery of the casing 1. Preferably the projections 29 and 30 on the casing 1 are shaped to snap into the recesses 27 and 28 on the cap 25.

As shown in FIG. 5, the casing 1 is provided with axially shaped grooves 31, 32, 33, 34 and 35 along its circumference. These grooves are situated with the same mutual angular spacing as the grooves or recesses 27 and 28 on the inner side of the cap 25. These grooves 31–35 on the outer side of the casing 1 cooperate with a projection 36 on the adjustment means 18 which projects inwardly. The grooves 31–35 and the projection 36 are shaped such that the adjustment means 18 can readily be rotated relative to the casing 1 by a user. The projection 36 cooperates with the grooves to releasably hold the casing 1 at any one of five detent positions with respect to the adjustment means, and to provide an audible click as the casing 1 is advanced from one detent position to the next.

A scale is provided on the outer side of the adjustment means 18 at the end adjacent the cap 25 (FIG. 1). This scale comprises a platform 37 with the number 0 thereon. Correspondingly, the cap 25 comprises a knob 38 to be situated opposite the platform 37. The arbitrary positioning of the cap 25 along the circumference of the casing and the corresponding positioning of the adjustment means 18 also relative to the circumference of the casing 1 renders it possible for the user always to be able to situate the knob 38 opposite the platform 37 before the adjustment is initiated.

The dosage unit of FIGS. 1–5 operates in the following manner. Upon positioning of the knob 38 opposite the platform 37 of the adjustment means 18, the desired dosing quantity is set by turning the cap 25 and therefore the casing 1 relative to the adjustment means 18. As a result, the nut member 13 is forced to follow the rotation, the abutment of said nut member 13 against the end of the casing 1 preventing a turning of the adjustment means 18 in the incorrect direction. The rotation of the nut member 13 relative to the piston rod member 8 moves the nut member 13 away from the cartridge by the thread 12, and the indicator moves axially away from the free end of the adjustment means 18. As a result, a coarse measuring scale 39 appears on the outside of the indicator 21. This scale can be configured to

indicate the dosing quantity in question in full turns of the adjustment means **18** relative to the knob **38** on the cap **25**, while the scale **40** on the end of the adjustment means adjacent the cap **25** indicates the dosing quantity by portions of a full rotation of the adjustment means **18** relative to the knob **38**.

When the desired dosing quantity has been set, the turning of the adjustment means **18** is stopped at a suitable location defined by the inner projection **36** being received in one of the grooves **31–35** on the outside of the casing **1**. Subsequently, the user removes the cap **25** and positions the dosage unit at the desired location to insert the needle **5**. Then the indicator **21** is forced back into the adjustment means **18** by pressing on the end button **22** until this movement is stopped by the abutment of the nut member **13** against the end of the casing **1** or the abutment of the end button **22** against the adjacent end of the adjustment means **18**. The pawl **11** prevents the piston rod member **8** from rotating, and the displacement of the indicator **21** therefore causes displacement of the piston rod member by a corresponding distance, whereby the piston of the cartridge is pressed towards the outlet end of the cartridge. As a result, a quantity of liquid is pressed out of the cartridge, said quantity corresponding to the quantity measured on the measuring scales. After completion of the injection of liquid, the dosage unit is of the same length as before the preadjustment and therefore it maintains an acceptable, uniform appearance.

A suitable choice of material allows the casing **1** to be transparent, whereby the user can always see whether liquid is left in the cartridge. The cap **25** ensures simultaneously that the contents of the cartridge are protected against sunlight. The various parts of the dosage unit are advantageously made of plastics by injection molding and are relatively easy to manufacture.

FIGS. **6** and **7** illustrate an alternate form of the indicator **21** and the associated nut member **13**. On the outside this indicator comprises a protrusion **41** received in a corresponding groove on the inside of the adjustment means **18**. At the end opposite the protrusion **41**, a circumferential groove **42** is provided for the fastening of a loose end knob (not shown) shaped like the end knob **22**.

Many modifications can be made to the first embodiment without thereby deviating from the scope of the invention. The piston rod member may, for instance, be of different cross sections depending on the shape of the ratchet device, and the piston rod member may be prevented from rotating by a suitable shaping of the opening through which the piston rod member passes into the casing **1**. Mating teeth may be provided on the end of the nut member **13** adjacent the casing **1** as well as on the abutting end of the casing **1**. These teeth are preferably shaped as cooperating barbs preventing a mutual rotation of the casing **1** and the nut member towards a stronger tension. These barbs allow a slight turning in the opposite direction.

As illustrated in FIG. **1**, the cap **25** is of a non-circular cross section at the end opposite the adjustment means **18** when said cap is secured on the dosage unit. In this manner it is easy to handle the cap during the mounting procedure. Furthermore, a clip **43** is provided which secures the dosage unit to a pocket in a manner similar to a fountain pen.

The second preferred embodiment of FIGS. **8–19** is similar in many respects to the first preferred embodiment described above. In view of these similarities, corresponding elements in the second embodiment are identified with the same reference numeral as in the first embodiment, with the addition of a prime. Points of similarity between the two embodiments will not be repeated, and the following discussion will focus on the differences between these embodiments.

As best shown in FIGS. **8**, **9** and **10**, the illustrated disposable syringe includes a removable cap **25'** which fits against the second housing element **18'**. The second housing element **18'** defines a projecting element **44'**, and the cap **25'** defines a mating recess **45'**. FIG. **10** shows the way in which the projecting element **44'** fits within the recess **45'** to define a zero position when the cap **25'** is moved against the second housing element **18'**. When it is desired to rotate the cap **25'** with respect to the second housing element **18'**, the cap **25'** is moved to the position shown in FIG. **9**, in which the projecting element **44'** is positioned outside of the recess **45'**, thereby allowing rotation.

The nut element **13'** is quite similar to that shown in FIGS. **6** and **7**, and the second housing element **18'** includes an internal rib **46'** that cooperates with the protrusion **41'** to define a stop position, beyond which the nut element **13'** cannot move. The pressure receiving element **22'** defines an array of internal ribs **47'** on its internal surfaces, and these ribs **47'** are configured to snap into and to engage the circumferential groove **42'** in the nut element **13'**. These ribs **47'** are best shown in FIGS. **11** and **18**. In this way assembly of the syringe is facilitated, without requiring adhesives of any type.

FIGS. **11** and **12** show the manner in which the first housing element **1'** includes a projection **29'** that is shaped to fit into any one of five equally spaced recesses **27'** in the cap **25'**.

As best shown in FIGS. **14**, **15** and **17**, the first housing element **1'** defines a circumferential lip **48'** at its forward end, as well as a circumferential array of lugs **49'**. The retaining cap **7'** defines a mating groove **50'**, and a circumferential array of mating recesses **51'**. When the retaining cap **7'** is snapped in place on the first housing element **1'** (FIG. **17**), the lip **48'** fits within the groove **50'** to hold the retaining cap **7'** securely in place axially. Similarly, the lugs **49'** engage respective ones of the recesses **51'** to prevent relative rotation between the retaining cap **7'** and the first housing element **1'**.

As best shown in FIGS. **14**, **15** and **16**, the piston rod element **8'** defines two diametrically opposed longitudinal grooves **9'**, and the first housing element **1'** includes two diametrically opposed pawls **11'**, each shaped to fit into a respective one of the grooves **9'** to prevent relative rotation between the piston rod element **8'** and the first housing element **1'**. Ribs **52'** (FIGS. **15** and **16**) are provided to engage the cartridge **2'** frictionally.

As best shown in FIGS. **11** and **14**, the first housing element **1'** also defines a raised lug **53'** which cooperates with five equally spaced grooves in the second housing element **18'** (not shown) to define five detented rotational positions of the first housing element **1'** with respect to the second housing element **18'**. As best shown in FIGS. **14** and **18**, the first housing element **1'** and the nut element **13'** define respective ramps **54'**, **55'**. These ramps are oriented to prevent relative rotation in a selected direction between the first housing element **1'** and the nut element **13'** when the ramps **54'**, **55'** engage one another so as to prevent excessive stresses on the pawls **11'**.

As mentioned above, the operation of the embodiment of FIGS. **8–18** is quite similar to that of the first

preferred embodiment, and will not be described again here.

In the first and second embodiments described above, the piston rod is in each case a two-part assembly made up of a piston rod element and a nut element. However, this is not essential for all syringes using the protective cap of this invention, and the third preferred embodiment shown in FIGS. 19–27 includes a one-piece piston rod.

The disposable syringe illustrated in FIGS. 19–27 comprises a first housing element **101** shaped to receive a liquid filled cartridge (see FIGS. 20, 23). The liquid filled cartridge is preferably of a conventional type and comprises at its front end a rubber membrane, which can be pierced by a needle, and at its rear end an axially displaceable piston. The rear end of the first housing element **101** comprises a relatively short external thread **102** capable of cooperating with an internal thread in a second housing element described below.

A needle assembly, comprising a hub **103**, a double pointed needle **104** and internal threads **105**, is screwed onto the front end of the first housing element **101**. This causes the rear end of the needle **104** to penetrate the rubber membrane of the liquid filled cartridge when the latter is pressed into position against the front end of the first housing element **101**.

The first housing element **101** is preferably made of a transparent plastic material, and it comprises five equally spaced longitudinally extending ribs **106** (see FIGS. 20 and 21). The disposable syringe further includes a second housing element **110** surrounding at least the rear end of the first housing element **101** and having an internal thread **111** that cooperates with the external thread **102** on the first housing element **101**. The mating threads on the first and second housing elements **101, 110** are configured such that clockwise rotation of the first housing element **101** with respect to the second housing element **110** causes the first housing element **101** to be axially displaced towards the rear end of the second housing element **110**. The second housing element **110** includes a rear end wall **112**, and the syringe further includes a central, axially displaceable piston rod **113**. The front end of the piston rod **113** comprises a collar **114**, and the rear end of the piston rod **113** extends through an opening **115** in the end wall **112** and terminates in a pressure receiving element **116**. A coil spring **117** surrounds the piston rod **113** and is tensioned between the collar **114** and the interior side of the end wall **112**. This coil spring **117** tends to press the front end of the piston rod **113** against the piston of the cartridge located within the first housing element **101**, and to maintain the pressure receiving element **116** in contact with the exterior of the end wall **112**.

The second housing element **110** also comprises a combined pawl and click mechanism **118**. This mechanism **118** extends into the interior of the second housing element **110** and includes a projection **119** having the shape of a saw tooth in contact with the exterior surface of the first housing element **101** and in particular the ribs **106** in such a manner that a counterclockwise rotation of the first housing element **101** relative to the second housing element **110** requires a predetermined force which is greater than the force required to cause clockwise rotation. The mechanism **118** is resiliently connected with the second housing element **110** in such a manner that a click is produced when the projection **119** slides over a rib **106** on the exterior of the first housing element **101**.

The second housing element **110** includes at its front end an axially extending recess **120**, which cooperates with an axially extending rib provided on a protecting cap described below. The second housing element **110** also defines two axially spaced annular grooves **121, 122** which are positioned on the interior side of the second housing element **110** near the front end. The grooves **121, 122** cooperate with an annular locking ring provided on the protecting cap described below.

As shown in FIGS. **21** and **22**, the second housing element **110** is composed of two parts **123, 124** which are interconnected with one another at a plane that extends axially of the second housing element **110**.

The disposable syringe further includes a protecting cap **130** which carries at its front end a clip **131**. The protecting cap **130** defines at an internal surface five axially extending grooves **132**, shaped to receive the ribs **106** provided on the exterior surface of the first housing element **101**. The mating ribs **106** and grooves **132** form splines that rotationally engage the protecting cap **130** with the first housing element **101**. For this reason, when the protecting cap **130** is positioned over the first housing element **101**, rotation of the protecting cap **130** automatically causes a similar rotation of the first housing element **101**.

The rear end of the protecting cap **130** includes a section **133** of a reduced diameter sized to fit within the front end of the second housing element **110**. At the rear end of the portion of the protecting cap **130** having the full diameter of the protecting cap **130**, there are provided a number of axially extending ribs **134**, and one of these ribs **135** is shaped as a projection which extends into the section **133** of reduced diameter. The projecting rib **135** is shaped to be inserted into the recess **120** so as to prevent relative rotation between the protecting cap **130** and the second housing element **110**.

The reduced diameter section **133** defines an external annular locking ring **136** that is shaped to fit into either one of the grooves **121** or **122** on the interior surface of the second housing element **110** (FIGS. **26** and **27**).

When delivered to the patient the syringe of FIGS. 19 through 27 is loaded with a liquid filled cartridge, and the protecting cap **130** is inserted in the second housing element **110** with the projecting rib **135** on the protecting cap **130** inserted into the recess **120** in the second housing element **110**. In this position, the annular rib **136** is located in the groove **122** (FIG. **26**) and the protecting cap **130** is prevented from rotating relative to the second housing element **110**.

Before setting the dose to be injected, the patient must axially displace the protecting cap **130** relative to the first housing element **101**, preferably to a position in which the annular rib **36** is located in the groove **121** (FIG. **27**). At this point, the patient is free to rotate the protecting cap **130** and the first housing element **101** to set the dose. By using the recess **120** as the zero point, the patient can select a desired dose by rotating the protecting cap **130** over an angle corresponding to a given number of the ribs **134** on the exterior surface of the protecting cap **130**. Rotation of the first housing element **101** will cause the piston rod **113** to be axially displaced towards the rear end of the second housing element **110**, thus axially displacing the pressure receiving element **116** from the exterior side of the end wall **112**. After the desired dosage has been selected, the protecting cap **130** is removed and the syringe is now prepared for an injection (FIG. **25**).

The injection is effected by depressing the pressure receiving element **116**. Such a depression will cause the piston of the cartridge to be axially moved towards the front end of the syringe, thereby delivering the desired preset dosage of liquid from the tip of the needle **104**. After the injection has been completed, the protecting cap **130** is reinserted on the end of the housing **101** with the rib **135** located in the recess **120**, and the syringe is again ready for presetting an injection of another preset dosage of liquid.

The piston rod **113** defines stop members **140** which cooperate with the interior surface of the end wall **112** if the piston rod **113** is axially displaced over a distance which is longer than acceptable. In this way, the stop members prevent the selection of a dosage that exceeds a predetermined value.

All three embodiments described above are adapted for use with a liquid filled cartridge. This is convenient for many applications, because the material for the first housing element can be chosen without concern for possible adverse reaction with the solution to be injected. However, for some applications, it may be preferable to eliminate the cartridge and use the first housing element with a suitable piston to contain the solution directly.

We claim:

1. In a disposable syringe for injecting a number of measured doses of a liquid, of the type comprising first and second housing elements coupled together to allow rotation of the first housing element with respect to the second housing element, said first housing element adapted to receive a quantity of liquid and comprising means for mounting a liquid outlet needle at a front end thereof, said second housing element having a rear end situated opposite the front end of the first housing element, the improvement comprising:

a piston rod disposed in the second housing element to move axially therein, said piston rod comprising a rod element and a nut element, said rod element coupled to the first housing element to move axially therein without relative rotation therewith, said nut element threaded to the rod element for telescoping movement therewith and configured to move axially in the second housing element without relative rotation therein; and

a pressure receiving element on the nut element;

said housing, rod, nut and pressure receiving elements cooperating such that relative rotation between the housing elements in a selected direction causes relative rotation between the rod and nut elements and thereby increases the effective length of the piston rod and causes the pressure receiving element to extend from the second housing element such that a measured quantity of liquid is expressed from the needle when the pressure receiving element is moved back toward the second housing element.

2. The invention of claim **1** wherein the first and second housing elements are coupled together for rotation without axial displacement therebetween.

3. The invention of claim **1** wherein the pressure receiving element defines a first stop surface that limits travel of the nut element inwardly, towards the first housing element.

4. The invention of claim **2** wherein the nut element defines an axially oriented scale positioned to indicate the axial position of the nut element with respect to the second housing element.

5. The invention of claim **4** wherein the scale is integrally formed on the nut element.

6. The invention of claim **1** wherein the first housing element is configured to receive a cartridge having a pierceable diaphragm at a front end thereof, a slideable piston at a rear end thereof, and containing the quantity of liquid.

7. The invention of claim **2** wherein the nut element defines at least one radially protruding, axially extending projection on an exterior portion thereof, and wherein the projection is received in an axially extending groove in an inner portion of the second housing element.

8. The invention of claim **1** wherein the nut element comprises a second stop surface configured to contact the second housing element to limit axial movement of the nut element out of the second housing element.

9. The invention of claim **1** wherein the nut element and the pressure receiving element are substantially axially symmetrically shaped, and wherein the pressure receiving element defines an outer diameter substantially equal to that of the second housing element.

10. The invention of claim **1** further comprising

a removable protective cap configured to receive the first housing element and substantially abut the second housing element while mounted on the first housing element; and

means for releasably coupling the protective cap and the first housing element for rotation together such that rotation of the protective cap with respect to the second housing element causes rotation of the first housing element with respect to the second housing element.

11. The invention of claim **10** wherein the substantially abutting front portion of the second housing element and rear portion of the protective cap together comprise scale means for measuring relative rotation of the protective cap with respect to the second housing element.

12. The invention of claim **11** further comprising means for providing detents at selected rotational positions of the first housing element with respect to the second housing element.

13. The invention of claim **12** wherein the coupling means allows the protective cap to receive the first housing element in multiple different angular positions of the protective cap with respect to the first housing element to allow the protective cap to be oriented at a selected position with respect to the second housing element, regardless of the detent rotational position of the first housing element in the second housing element.

14. The invention of claim **10** wherein the substantially abutting front portion of the second housing element and rear portion of the protective cap together comprise interlocking means for defining a selected angular position of the protective cap with respect to the second housing element.

15. The invention of claim **14** wherein the interlocking means comprises a recess on the rear portion of the protective cap and a projection on the front portion of the second housing element, said projection shaped to fit into the recess to define the selected angular position.

16. The invention of claim **1** wherein the rod element defines at least one toothed axial groove, and wherein the rod element is coupled to the first housing element by at least one pawl that rides in the groove to prevent rotation of the rod element in the first housing element,

said pawl engaging the toothed groove to prevent retraction of the rod element.

17. The invention of claim 16 wherein the at least one groove in the rod element comprises two diametrically opposed grooves, and wherein the at least one pawl comprises two pawls, one riding in each of the grooves.

18. The invention of claim 16 wherein the liquid is contained in a cartridge and wherein the first housing element comprises a locking ring that snaps in place to lock the cartridge within the first housing element.

19. The invention of claim 18 wherein the locking ring mechanically interlocks with a mating portion of the first housing element to prevent rotation therebetween.

20. In a disposable syringe for injecting a number of measured doses of a liquid, of the type comprising first and second housing elements coupled together to allow rotation of the first housing element with respect to the second housing element, said first housing element adapted to receive a quantity of liquid and comprising means for mounting a liquid outlet needle at a front end thereof, said second housing element having a rear end situated opposite the front end of the first housing element, the improvement comprising:

a piston rod disposed in the second housing element to move axially therein, said piston rod comprising a piston actuating end and a force receiving end, said force receiving end positioned at the rear end of the second housing element when in an initial position;

means, responsive to relative rotation between the first and second housing elements, for causing the force receiving end of the piston rod to move away from the initial position to preset a dose to be delivered through the needle when the force receiving end is returned to the initial position;

a protective cap removably mounted over the front end of the first housing element to protect the needle; and

means for releasably coupling the protective cap and the first housing element for rotation together such that rotation of the protective cap with respect to the second housing element causes rotation of the first housing element with respect to the second housing element.

21. The invention of claim 20 wherein the protective cap is configured to receive the first housing element such that a front portion of the second housing element substantially abuts a rear portion of the protective cap when the protective cap is mounted in place over the first housing element.

22. The invention of claim 21 wherein the substantially abutting front portion of the second housing element and rear portion of the protective cap together comprise scale means for measuring relative rotation of the protective cap with respect to the second housing element.

23. The invention of claim 22 wherein the scale means comprises a circumferential scale on the rear portion of the protective cap and a marker on the front portion of the second housing element.

24. The invention of claim 20 wherein the releasably coupling means comprises a set of interengaging splines on the protective cap and the first housing element.

25. The invention of claim 24 wherein the splines are configured to allow the protective cap to receive the first housing element in multiple different angular positions of the protective cap with respect to the first housing element.

26. The invention of claim 21 wherein the substantially abutting front portion of the second housing element and rear portion of the protective cap together comprise interlocking means for defining a selected angular position of the protective cap with respect to the second housing element.

27. The invention of claim 26 wherein the interlocking means comprises a recess on the rear portion of the protective cap and a projection on the front portion of the second housing element, said projection shaped to fit into the recess to define the selected angular position.

28. The invention of claim 20 wherein the piston rod comprises a rod element and a nut element threadedly engaged with the rod element, and wherein the nut element is configured to move axially without rotating in the second housing element.

29. The invention of claim 28 further comprising ratchet means for preventing the rod element from retracting from the first housing element while allowing the rod element to move into the first housing element.

30. The invention of claim 20 wherein the first housing element is configured to receive a cartridge having a pierceable diaphragm at a front end thereof, a slideable piston at a rear end thereof, and containing the quantity of liquid.

* * * * *

EXHIBIT 8

REDACTED